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Journal of Hearing Science®

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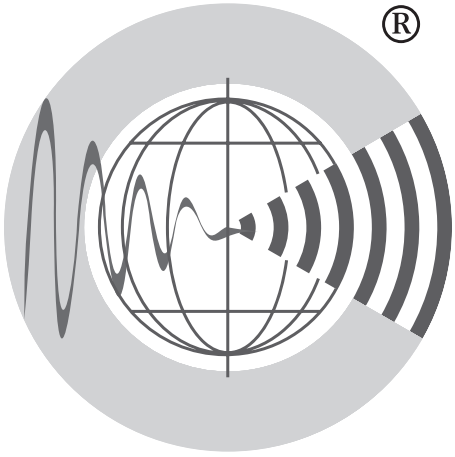

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Dear Colleagues,

In this issue of the *Journal of Hearing Science*, we bring together work that spans the full arc of hearing care – from foundational audiological methodology to evolving clinical candidacy.

We open with a review revisiting masking techniques and the application of Lidén's formulas to bone conduction speech audiometry. Audiological and otological interventions need a solid diagnostic base, so discussing them is always important. As clinical workflows modernise and test batteries expand, returning to first principles is a practical reminder that accurate interpretation still depends on rigorous technique.

Two original contributions next highlight how hearing science advances when measurement, biology, and lived experience are considered together. The first explores the feasibility and acceptability of a non-invasive sound therapy device for alleviating tinnitus symptoms in military veterans. Veterans are an important population in which the symptom burden is often complex and care pathways must be both effective and acceptable. At the other end of the translational spectrum, wideband acoustic immittance is paired with histopathology in a mouse model of otitis media, strengthening the bridge between middle ear mechanics and underlying tissue changes, and helping to clarify what our clinical metrics are actually telling us.

The psychosocial context of auditory difficulties is brought into sharp focus in a study on family cohesion and flexibility in cases where children have central auditory processing disorder. The study is another reminder that auditory diagnoses reverberate beyond the basic audiogram, involving family dynamics, availability of resources for coping, and the practical realities of daily communication.

Our concluding case report deals with one of the most dynamic frontiers in contemporary otology: a case of partial deafness in which there was low-frequency cochlear implant stimulation but preserved high-frequency hearing. This work invites thoughtful discussion about how we define candidacy and how broadly we can extend benefits while protecting residual function.

With kind regards and greetings,

Prof. Henryk Skarzynski, M.D., Ph.D., Dr. h.c. multi

Review papers

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MASKING TECHNIQUES REVISITED: APPLICATION OF LIDÉN'S FORMULAS IN BONE CONDUCTION SPEECH AUDIOMETRY

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Abstract

Introduction: Bone conduction speech audiometry is a complementary tool required by many otologists, particularly in assessing cochlear reserve and estimating postoperative results in patients undergoing stapedectomy. However, when clinical masking of the non-test ear is needed for these tests, it introduces a significant methodological challenge. This study aims to establish a systematic approach for determining safe and effective masking levels in bone conduction speech audiometry. In this context, the proposed framework offers quantitative tools designed to help reduce the risk of masking dilemmas, which are a persistent challenge in audiologic practice.

Material and methods: Adaptation and application of Lidén's formulas to determine the minimum and maximum masking levels for bone conduction speech audiometry and analysis of four frequently encountered audiometric configurations.

Results: The minimum and maximum masking levels for each configuration were determined. In cases of large ear-bone gaps in the non-test ear, and/or good bone conduction thresholds in the test ear, masking at supra-threshold levels may be difficult due to the risk of overmasking. In one or more of these configurations, a masking dilemma is sometimes detected at levels close to the speech recognition threshold. In such challenging situations, we recommend the use of insert earphones to extend the range of safe stimulus levels and masking levels that can be presented to the patient.

Conclusions: Speech audiometry holds considerable predictive value for otologic surgeons, so it is important to use techniques that minimise the risks of cross-hearing and inappropriate masking. These limitations are important when using bone-conduction stimulation and need to be carefully evaluated. This paper shows how Lidén's formulas can be used for calculating safe masking levels.

Keywords: diagnostic techniques • speech audiometry • clinical masking • bone conduction • Lidén's formulas

PONOWNE SPOJRZENIE NA TECHNIKI MASKOWANIA: ZASTOSOWANIE WZORÓW LIDÉNA W AUDIOMETRII SŁOWNEJ DLA PRZEWODNICTWA KOSTNEGO

Streszczenie

Wprowadzenie: Audiometria słowna dla przewodnictwa kostnego jest narzędziem uzupełniającym wymaganym przez wielu otologów, szczególnie w ocenie rezerwy ślimakowej i szacowaniu wyników pooperacyjnych u pacjentów poddanych stapedektomii. Jednak gdy do wykonania tych badań konieczne jest kliniczne maskowanie ucha niepoddawanego badaniu, stanowi to poważne wyzwanie metodologiczne. Niniejsze badanie ma na celu ustalenie podejścia systematycznego do określania bezpiecznych i skutecznych poziomów maskowania w audiometrii słownej dla przewodnictwa kostnego. W tym kontekście proponowane ramy oferują narzędzia ilościowe zaprojektowane w celu zmniejszenia problemów związanych z maskowaniem, które stanowią stałe wyzwanie w praktyce audiologicznej.

Materiał i metody: Adaptacja i zastosowanie wzorów Lidéna do określenia minimalnych i maksymalnych poziomów maskowania w audiometrii dla przewodnictwa kostnego oraz analiza czterech często spotykanych konfiguracji audiometrycznych.

Wyniki: Określono minimalne i maksymalne poziomy maskowania dla każdej konfiguracji. W przypadku dużej różnicy między przewodnictwem powietrznym a kostnym w uchu niebadanym i/lub prawidłowych progów przewodnictwa kostnego w uchu badanym maskowanie na poziomach powyżej progu może być trudne ze względu na ryzyko nadmiernego maskowania. W jednej lub kilku z tych konfiguracji czasami pojawia się problem maskowania na poziomach zbliżonych do progu rozpoznawania mowy. W tych sytuacjach zalecamy stosowanie słuchawek dousznych w celu poszerzenia zakresu bezpiecznych poziomów bodźców i poziomów maskowania, które można zastosować u pacjenta.

Wnioski: Audiometria słowna ma duże znaczenie prognostyczne dla otochirurgów, dlatego ważne jest stosowanie technik minimalizujących ryzyko słyszenia krzyżowego i nieodpowiedniego maskowania. Ograniczenia te są istotne w przypadku stosowania stymulacji w przewodnictwie

kostnym i wymagają dokładnej oceny. Niniejszy artykuł pokazuje, w jaki sposób można wykorzystać wzory Lidéna do obliczania bezpiecznych poziomów maskowania.

Słowa kluczowe: techniki diagnostyczne • audiometria słowna • maskowanie kliniczne • przewodnictwo kostne • wzory Lidéna

Key to abbreviations	
ABG	air-bone gap
BEST_BC_NTE	best bone-conduction threshold for non-test ear
BEST_BC_TE	best bone-conduction threshold for test ear
IA_AC	interaural attenuation for air conduction
IA_BC	interaural attenuation for bone conduction
MAX_GAP_NTE	maximum air-bone gap in non-test ear
MAX_MASK	maximum masking level
MID_MASK	mid masking level
MIN_MASK	minimum masking level
NTE	non-test ear
PL_TE	presentation level at test ear
PTA	pure tone average
SDT	speech detection threshold
SRT	speech recognition threshold
TE	test ear
WRS	word recognition score

Introduction

Despite a small number of papers in the field, some authors have highlighted the usefulness of assessing bone conduction speech thresholds. Kruger & Mazor [1] noted that the speech detection threshold (SDT) and speech recognition threshold (SRT), typically measured through air conduction, can also be determined for bone conduction. They argue that in this way it is feasible to detect the presence of an air–bone gap and estimate its magnitude in cases where it is difficult to obtain responses through pure tones, such as in children or other hard-to-test patients. Bone-conduction SRT correlates well with the average bone thresholds at 500, 1000, and 2000 Hz, whereas bone-conduction SDT demonstrates good correlation with the bone threshold at 250 Hz.

The use of bone-conduction speech thresholds in situations where pure-tone audiometry is difficult to perform is a useful approach for evaluating the likely outcomes of stapedectomy surgeries. Goetzinger & Proud [2] proposed using the bone-conduction SRT as a complement to bone-conduction pure tone audiometry. They collected data from 353 ears in patients aged 5–64 years. The relationship between the bone conduction SRT and the bone-conduction pure-tone average (PTA) exhibited a high positive correlation ($r = 0.90$), comparable to that found for air conduction stimulation. Merrel et al. [3] emphasised the usefulness of bone and air conduction speech thresholds, particularly in pediatric cases, allowing for better differentiation between conductive and sensorineural hearing loss than does pure-tone audiometry. Goetzinger & Proud [2] also reported obtaining the word recognition score (WRS) at a level 25 dB above the SRT, with scores of 90–100% being typical of normal-hearing individuals and patients with conductive hearing loss, whereas individuals with sensorineural losses exhibited varying degrees of discrimination difficulty. However, the core of their work was to explain the utility of obtaining speech recognition thresholds.

In other work, Hahlbrock [4] explained that bone-conduction pure-tone audiometry may yield erroneous results at frequencies below 1000 Hz due to the perception of the tone through tactile vibration rather than through the auditory system. Differentiating between real auditory perception and tactile sensation is not always possible with a yes/no response method like pure-tone audiometry. This may result in an overestimation of cochlear reserve, and he therefore suggested the use of bone-conduction speech audiometry as a more appropriate technique. The same author cited earlier work by Tato & Alfaro [5] who suggested that using bone-conduction speech discrimination provides validation of an air-conduction test. They reported that bone-conduction speech discrimination scores obtained at a comfortable listening level had great diagnostic value in terms of the degree of sensorineural deterioration, and considered that patients with recognition scores above 80% were good candidates for surgery.

Robinson & Kasden [6,7] pointed out that preoperative bone-conduction speech discrimination is an accurate way of measuring cochlear reserve in patients with otosclerosis. They illustrated several cases where the use of bone-conduction recognition scores was an excellent predictor of postoperative outcomes. However, they made an important caveat regarding the feasibility of performing such studies, which relates to the maximum stimulation level allowed by both the audiometer and bone vibrator. For bone conduction, the maximum stimulus level for speech was 55 dB HL (in current audiometers, it is 60 dB HL), imposing an upper limit on presentation levels. The authors said that reaching higher stimulus levels required an additional amplifier and bone transducer capable of delivering a more powerful and distortion-free signal. Such a necessity may explain the limited spread of this methodology, given the requirement for an additional amplifier whose output must be calibrated separately. WRS values were obtained at the most comfortable loudness level for the TE, with the maximum acceptable masking applied to the NTE.

In related technical work, Barry & Gaddis [8] did not criticise the use of bone-conduction speech audiometry per se, but warned about the maximum stimulus presentation levels beyond which appreciable distortion may occur. In addition to the limitations imposed by the maximum

level of speech stimulus that can be presented through bone conduction, the most important limitation to consider is the risk of cross-hearing.

Given these technical and methodological challenges, the present work aims to establish a reliable framework for calculating, using Lidén's formulas, safe masking levels in bone conduction speech audiometry. By analysing common audiometric configurations, this study seeks to support clinicians in minimising the risk of overmasking and cross-hearing, thereby improving the accuracy and clinical utility of speech-based bone conduction assessments. Although there are well-established references regarding the clinical application of masking for pure-tone audiometry and airconduction speech audiometry, little has been written about the application of masking in boneconduction speech audiometry. Since masking continues to be widely used, it is important to analyse it in detail and to construct a solid theoretical foundation for its use.

Material and methods

The need for masking in bone-conduction speech audiometry

The abbreviations used here are derived from those used by Yacullo [9] and Turner [10]. According to the theory of clinical masking in speech audiometry, the interaural attenuation (IA) for a stimulus applied via bone conduction is very low. It is generally assumed, as a conservative criterion, to be zero (IA_BC = 0). Therefore, when speech material is presented to the test ear (TE) at a certain presentation level (PL_TE), that same stimulus level also reaches the non-test ear (NTE). Hence, if the level presented to the TE exceeds the best bone-conduction threshold of the NTE, the information reaching this ear may be enough for recognition. Consequently, the basic criterion for deciding the need for masking in bone--conduction speech audiometry is:

$$\begin{aligned} &PL\_TE\text{-}IA\_BC \geq BEST\_BC\_NTE \\ &\text{and, since } IA\_BC = 0, \\ &PL\_TE \geq BEST\_BC\_NTE \end{aligned} \quad (1)$$

In this formula, it is considered that the best bone conduction threshold of the non-test ear could be responsible for speech recognition by the non-test ear. This criterion is included in the ASHA [11] publication. This implies that masking should be applied whenever the presentation level of the stimulus in the test ear exceeds the best bone conduction threshold in the non-test ear within the 500–4000 Hz range.

Lidén's formulas for minimum and maximum masking levels in bone conduction

If masking is required, the level to be applied should be enough to prevent the non-test ear from recognising the stimulus presented to the test ear, but not so intense as to cause overmasking. Such overmasking occurs when the masking noise applied to the non-test ear crosses over and masks the perception of the stimulus in the test ear. Following the same rationale used in speech audiometry with air conduction, works by Yacullo [9] and Alonso et al. [12] showed that it is advisable to place the masking level in the mid-plateau region. The plateau is bounded by minimum and maximum masking values.

Lidén's formulas [13] are the theoretical basis for masking of pure tone stimuli via both air and bone conduction, as well as speech stimuli via air conduction. They can also be applied to bone conduction to determine the minimum and maximum masking levels.

$$MIN\_MASK = PL\_TE - IA\_BC + MAX\_GAP\_NTE$$
$$MAX\_MASK = BEST\_BC\_TE + IA\_AC - 5 \text{ dB}$$

IA_BC refers to the interaural attenuation value for stimuli presented by bone conduction, which is generally considered to be 0 dB. On the other hand, IA_AC is the interaural attenuation for stimuli delivered through air conduction using headphones, and its value depends on the type of transducer used for masking. Considering that for bone conduction, IA_BC = 0, the above expressions can be simplified as follows:

$$MIN\_MASK = PL\_TE + MAX\_GAP\_NTE \quad (2)$$
$$MAX\_MASK = BEST\_BC\_TE + IA\_AC - 5 \text{ dB} \quad (3)$$

Since masking is always applied through headphones, the IA value to be used in the MAX_MASK formula corresponds to this type of transducer. Therefore, IA_AC = 40 dB (or 60 dB if insert earphones are used). The term MAX_GAP_NTE refers to the maximum air-bone gap in the range 500 to 4000 Hz in the non-test ear.

These formulas demonstrate that, for a given presentation level, the relevant variables to consider in the pure tone audiogram are the largest air-bone gap in the non-test ear and the best bone conduction threshold in the test ear. A reduced air-bone gap in the non-test ear requires a lower minimum masking level; conversely, a poorer bone conduction threshold in the test ear allows for a higher maximum masking level without introducing overmasking. The optimal situation occurs when MAX_GAP_NTE = 0 and BC_TE is high. The worst-case scenario is the opposite, where MAX_GAP_NTE is maximal and BC_TE = 0. Yacullo [14] recommends using a masking level in the middle of both limits, so that

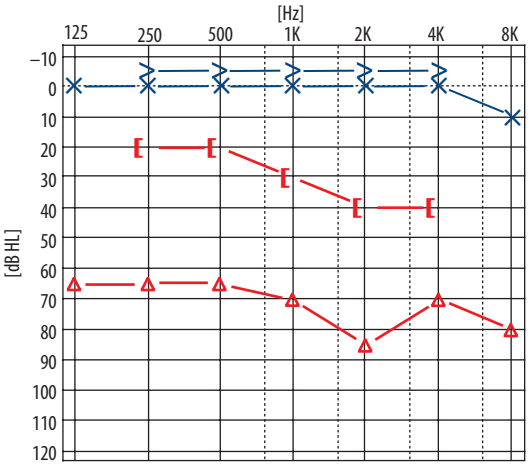
$$MID\_MASK = (MIN\_MASK + MAX\_MASK)/2$$

Occlusion effect in bone conduction speech audiometry

Gelfand & Calandruccio [15] emphasised the need to account for the occlusion effect when calculating masking levels for bone conduction speech audiometry. Based on the measurements reported by Klodd & Edgerton [16], it is recommended to adjust the formula for minimum masking as follows:

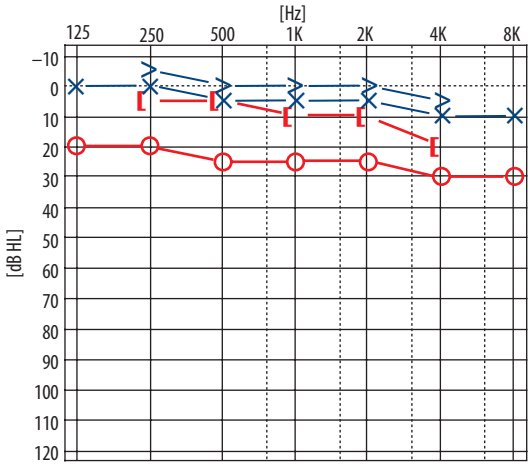
$$MIN\_MASK = PL\_TE + MAX\_GAP\_NTE + OE \quad (2')$$

This corresponds to formula (2) with the addition of a compensation term for the occlusion effect. These authors recommend using an OE value of 18 dB when the bone vibrator is placed on the mastoid and 23 dB when placed



BEST_BC_NTE	−5
MAX_GAP_NTE	5
BEST_BC_TE	20

Figure 1. Mixed hearing loss in the test ear; normal hearing in the non-test ear. The numbers below the audiogram list the variables used in the formula



BEST_BC_NTE	0
MAX_GAP_NTE	5
BEST_BC_TE	5

Figure 2. Conductive hearing loss in the test ear. Normal non-test ear

on the vertex. Their conclusions were based on measurements obtained using circumaural headphones. To date, no comparable measurements have been found for insert earphones. However, considering that the occlusion effect for tonal stimuli only affects the 250 Hz frequency when this kind of transducer is used [17], it may be concluded that, for them, the influence (if any) would be minimal and practically negligible. This additionally substantiates the use of insert earphones for masking in bone conduction speech audiometry, particularly when they are deeply inserted in the ear canal, as this minimises the occlusion effect [18]. Furthermore, it should be remarked that if the non-test ear presents a conductive component, compensation for the occlusion effect is not necessary [17].

Results

Application of Lidén formulas to different audiogram configurations

In the following cases, masking will be applied to obtain bone conduction speech audiometry in the right ear (TE). Four audiometric configurations frequently observed in clinical practice are analysed, illustrating the influence of multiple variables that must be considered. It is also assumed that a circumaural earphone is used for masking, unless another option is explicitly stated. The tabulated numbers below each audiogram show the variables used in the formulas. Formula (1) is used to check if masking is required, and formulas (2 or 2') and (3) are for MIN_MASK and MAX_MASK calculations.

Case 1. TE: mixed hearing loss; NTE: normal hearing (Figure 1)

Need for masking
PL_TE ≥ BEST_BC_NTE
PL_TE ≥ – 5 dB.

This means that for any stimulus level presented to the right ear (TE), masking should be applied.

Minimum masking level
MIN_MASK = PL_TE + MAX_GAP_NTE + OE
MIN_MASK = PL_TE + 5 dB + 18 dB = PL_TE + 23 dB

Maximum masking level
MAX_MASK = BEST_BC_TE + IA_AC – 5 dB
MAX_MASK = 20 + 40 dB – 5 dB = 55 dB.

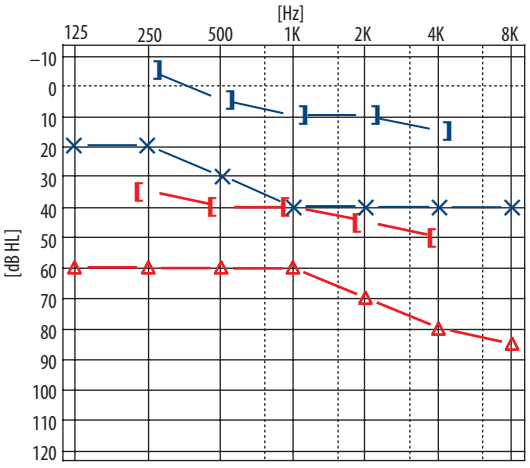
In this example, it is feasible to obtain bone-conduction SRT close to the bone-conduction PTA (30 dB). Obtaining some WRS at a supra-threshold level requires increasing the presentation level. If the presentation level at the TE is 40 dB, then MIN_MASK = 40 + 5 + 18 = 63 dB. The MIN_MASK is greater than the MAX_MASK. This is a masking dilemma: the minimum masking required is greater than the maximum permissible. The use of an insert earphone for masking delivery in the NTE can raise by 20 dB the maximum masking allowed. In this case, the applicable allowed masking values are from 63 to 75 dB.

Case 2. Single-sided hearing loss. TE: conductive hearing loss; NTE: normal hearing (Figure 2)

Need for masking
PL_TE ≥ BEST_BC_NTE
PL_TE ≥ 0

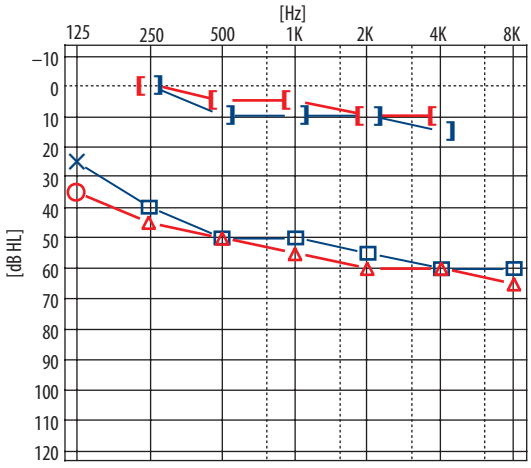
Thus, for any stimulus level presented to the right ear (TE), masking should be applied.

Minimum masking level
MIN_MASK = PL_TE + MAX_GAP_NTE + OE
MIN_MASK = PL_TE + 5 dB + 18 dB = PL_TE + 23 dB



BEST_BC_NTE	5
MAX_GAP_NTE	30
BEST_BC_TE	40

Figure 3. Mixed hearing loss in the test ear; conductive loss in the non-test ear



BEST_BC_NTE	10
MAX_GAP_NTE	45
BEST_BC_TE	5

Figure 4. Bilateral conductive hearing loss

Maximum masking level
MAX_MASK = BEST_BC_TE + IA_AC – 5 dB
MAX_MASK = 5 + 40 dB – 5 dB = 40 dB

There should be no issue obtaining the SRT in the right ear (TE) with presentation levels close to the bone PTA (10 dB). If PL_TE exceeds 20 dB, there is a risk of masking dilemma. Again, the use of insert earphones increases the MAX_MASK value. This is useful to obtain WRS at supra-threshold levels. For a 25 dB presentation level, using insert earphones for masking would increase MAX_MASK to 60 dB, yielding a range of 48 to 60 dB for allowed masking intensities.

Case 3. TE: mixed hearing loss; NTE: conductive hearing loss (Figure 3)

Need for masking
PL_TE ≥ BEST_AC_NTE
PL_TE ≥ 5 dB

For any presentation level equal to or greater than 5 dB, masking is required.

Minimum masking level
As the NTE has a conductive component, consideration of the occlusion effect is not required.
MIN_MASK = PL_TE + MAX_GAP_NTE
MIN_MASK = PL_TE + 30 dB

Maximum masking level
MAX_MASK = BEST_BC_TE + IA_AC – 5 dB
MAX_MASK = 40 + 40 dB – 5 dB = 75 dB

For a presentation level close to the SRT (assuming it is close to bone-conduction PTA) of 35 dB, the minimum masking level would be 65 dB. Under these conditions, a 70 dB masking level can be applied. For WRS at supra-threshold levels, a masking dilemma would likely occur. To avoid this, the use of insert earphones for masking is recommended. In that case, the maximum permissible masking level would be:

MAX_MASK = 40 + 60 dB – 5 dB = 95 dB

Case 4. Bilateral conductive hearing loss (Figure 4)

Need for masking
PL_TE ≥ BEST_BC_NTE
PL_TE ≥ 10 dB

Again, for any presentation level equal to or greater than 10 dB, masking is required.

Minimum masking level
MIN_MASK = PL_TE + MAX_GAP_NTE
MIN_MASK = PL_TE + 45 dB

Maximum masking level
MAX_MASK = BEST_BC_TE + IA_AC – 5 dB
MAX_MASK = 5 dB + 40 dB – 5 dB = 40 dB

This represents a masking dilemma, as the minimum masking level required exceeds the maximum permissible level. Yacullo [14] specifically analysed the case of speech recognition score determination in the context of a potential masking dilemma, indicating that the possible effects of overmasking in this type of test should be considered. Predictions about overmasking assume an interaural attenuation (IA) of 40 dB for speech with supra-aural headphones or 60 dB with insert earphones. It is imperative to remember that this is a highly conservative estimate, based on the lowest IA values reported in the literature. However, it is possible that the actual IA value for a given patient may be greater than this conservative estimate. If that is the case, the MAX_MASK would be higher, thus masking could be applied without the risk of overmasking. If the masker crosses over to the test ear,

it is necessary to assess the effects that overmasking might have on the patient's performance. It is important to recall that the evaluation intended is speech recognition at supra-threshold presentation levels. Therefore, we must ask what effect the crossover of masking noise from the non-test ear (NTE) to the test ear (TE) might have on the patient's supra-threshold performance.

The presence of masking noise in the TE will reduce the signal-to-noise ratio (SNR) in that ear; as a result, the crossover of the masking noise may potentially reduce supra-threshold speech recognition ability. However, it is important to emphasise that the objective of supra-threshold discrimination testing is to estimate the maximum discrimination score, that is, the maximum percentage of recognition for phonetically balanced word lists. If the patient demonstrates normal word recognition ability (90–100%) in the presence of masking, there is no evidence of overmasking, since it did not affect the outcome. In that case, the goal of evaluating speech recognition at a supra-threshold level has been fully achieved. On the other hand, if the patient exhibits a reduced recognition score (below 90%), overmasking may have occurred. This non-optimal score may be due either to overmasking or to an actual reduction in speech recognition ability. Therefore, Yacullo [14] recommends advising on this possibility in the test report.

Discussion

This article addresses the importance of using appropriate masking techniques when evaluating speech thresholds and word recognition scores via bone conduction. It is important to distinguish between pure-tone and speech masking procedures. In pure-tone audiometry, a psychoacoustic method such as the Plateau approach is generally considered appropriate. By contrast, speech audiometry – whether for speech recognition threshold (SRT) or word recognition score (WRS) determination – requires calculating the appropriate masking level for each presentation level. Consequently, speech masking is typically regarded as an acoustic method [13]. However, clinicians frequently overlook the inherently dynamic and broadband characteristics of speech stimuli, as well as the necessity of adopting a tailored methodological approach that accounts for the contribution of distinct frequency bands to speech recognition.

Given the limited literature on this subject, studying the issue requires a specific approach that considers the foundational principles of clinical masking theory. Since interaural attenuation for bone conduction is virtually negligible, masking is often needed. Additionally, the limitations inherent to this technique should be acknowledged, particularly the high likelihood of overmasking. As Floyd [17] has emphasised, the SRT results obtained through bone conduction should be interpreted with extreme caution. In cases 1 and 2, the absence or minimal air-bone gap in the non-test ear means that the minimum masking level required is approximately equal to the stimulus level presented to the TE plus the occlusion effect compensation. Cases 3 and 4 show scenarios with significant air-bone gaps in the non-test ear, requiring higher minimum masking levels and posing greater challenges, although compensation for the occlusion effect is not needed. In case 4, a bilateral

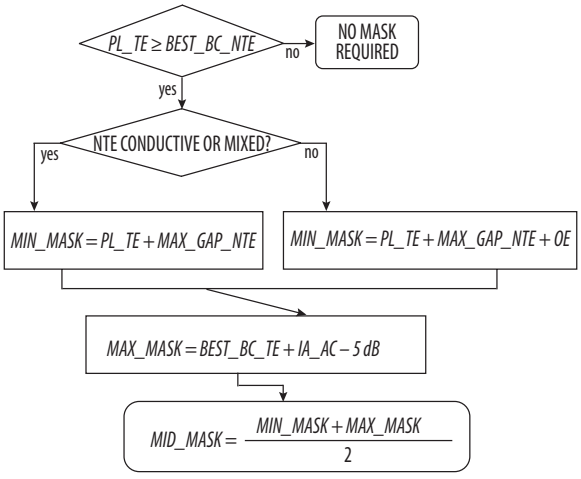


Figure 5. Flow diagram showing the complete procedure

conductive hearing loss, no corrections are required for the Lidén formulas, but it is strongly recommended to use insert phones for masking and the correct value of IA for this type of transducer (at least 60 dB).

When assessing the need for masking and determining appropriate masking levels for speech stimuli presented through bone conduction, applying Lidén's formulas facilitates the analysis of various cases. When dealing with bone-conducted speech stimuli, it is important to take into account the limitations imposed by the maximum output level of the audiometer, which constrain the ability to measure WRS at levels substantially above the SRT. Often, the application of high stimulus levels is restricted because the masking required to prevent cross-hearing would exceed the maximum permissible levels to avoid overmasking, leading to a masking dilemma. All the cases reviewed here demonstrate that the limited range of applicable masking levels yields a restricted range of test stimuli.

This finding strongly reinforces the recommendation to use insert earphones for masking of speech via bone conduction, as these transducers offer approximately 20 dB greater interaural attenuation compared to supra-aural headphones. This extra attenuation significantly broadens the effective range for both masking levels and test stimuli.

For evaluating potential surgical outcomes, pre- and postoperative assessments of SRT (or SDT) could serve as valid tools and are generally feasible when effective masking levels are appropriately applied. To obtain WRS at supra-threshold levels, it is crucial to verify the absence of overmasking. If possible, reporting WRS values at levels above the threshold is appropriate; however, if overmasking precludes this, the SRT may still provide a reliable alternative for predicting postoperative results. By considering preoperative air-conduction WRS values, one can estimate the anticipated postoperative discrimination outcomes. The perceptual characteristics of hearing loss, such as the rollover phenomenon, may be demonstrated through air-conduction speech audiometry without bone-conduction testing. To evaluate potential surgical outcomes, predicting

the closure of the air-bone gap at the SRT level may be enough. This would indicate the expected dB HL at which the new air-conduction SRT might be found, assuming that the air-bone GAP is closed. The maximum discrimination score should remain unchanged, and a similar shift in dB in the stimulus level at which it occurs may be predicted.

Figure 5 presents a flow diagram that illustrates the complete procedure, including the criterion for determining whether masking is required and the specification of the minimum and maximum masking levels.

By systematically analysing common audiometric configurations, this approach provides a clinical tool that supports otologists and audiologists in minimising masking errors. Importantly, accurate masking has direct real-world implications: it enhances the reliability of cochlear reserve assessment, informs candidacy for stapedectomy, and improves the prediction of postoperative outcomes in otosclerosis and other middleear pathologies. In this way, the proposed framework seeks to bridge a critical methodological gap and expand the practical utility of boneconduction speech audiometry in everyday clinical practice.

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EXPLORING THE FEASIBILITY AND ACCEPTABILITY OF A NON-INVASIVE SOUND THERAPY DEVICE IN REDUCING SYMPTOMS OF TINNITUS IN MILITARY VETERANS

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Abstract

Introduction: The prevalence of tinnitus in veterans is higher than in the general population and can profoundly affect daily life. Tinnitus has been associated with psychological difficulties and may result in functional impairment. Currently, no sound therapy has been widely validated as an effective option for tinnitus management. Given the profound impact of tinnitus, and its economic burden and treatment barriers, it is important to explore new approaches. Sound therapy technologies are readily accepted due to their simplicity and non-invasiveness, but there is limited research exploring sound therapy in veterans. Here we explore the feasibility and acceptability of a non-invasive management option.

Material and methods: This feasibility and acceptability study included 20 UK military veterans who trialled a non-invasive device, TinniSoothe, for 1 or 2 months. The device is a small sound-generating module designed to be worn on a lanyard or clip during the day and placed in a docking station at night. It allows users to adjust both frequency and volume according to personal preferences, and while docked at night it continues to emit sound into the nearby environment. Participants were instructed to complete a pre-intervention, post-intervention, and 2-month follow-up questionnaire which included measures of tinnitus, mental health, and physical health.

Results: All participants (20 veterans, mean age = 51.3, *SD* = 7.7, 80% male) used the device for the 1-month intervention period, with no dropouts or serious adverse events. The majority (75%) elected to keep the device after 1 month, and 80% said they would recommend it to friends and family. However, at 2 months, just 13 participants reported ongoing device use. From baseline to post-intervention and follow-up, participants reported significant reductions in tinnitus symptoms. Although there was a significant overall effect of time on sleep disturbances, pairwise comparisons did not show significant changes between specific timepoints. No significant differences were observed in the remaining outcomes.

Conclusions: This study indicates that the TinniSoothe device shows a degree of feasibility and acceptability for tinnitus management in veterans and there is some evidence supporting its efficacy. However, after 2 months 65% of the participants were still active users, indicating that further research exploring its effectiveness is necessary.

Keywords: tinnitus • wearable technology • sound therapy

BADANIE MOŻLIWOŚCI ZASTOSOWANIA I AKCEPTOWALNOŚCI NIEINWAZYJNEGO URZĄDZENIA DO TERAPII DŹWIĘKIEM W ZMNIEJSZANIU OBJAWÓW SZUMÓW USZNYCH U WETERANÓW WOJSKOWYCH

Streszczenie

Wprowadzenie: Częstość występowania szumów usznych u weteranów wojskowych jest wyższa niż w populacji ogólnej i może mieć głęboki wpływ na codzienne życie. Szumy uszne mogą skutkować trudnościami psychologicznymi i negatywnie wpływać na codzienne funkcjonowanie. Obecnie żadna terapia dźwiękowa nie została powszechnie uznana za skuteczną metodę leczenia szumów usznych. Biorąc pod uwagę głęboki wpływ szumów usznych, ich koszty ekonomiczne oraz trudności w leczeniu, ważne jest poszukiwanie nowych skutecznych metod. Technologie stosowane w terapii dźwiękiem są chętnie akceptowane ze względu na swoją prostotę i nieinwazyjność, jednak istnieje ograniczona liczba badań dotyczących terapii dźwiękiem u weteranów. W niniejszym artykule badamy możliwości zastosowania i akceptowalność nieinwazyjnej metody leczenia.

Materiał i metody: W badaniu wzięło udział 20 brytyjskich weteranów wojskowych, którzy przez 1 lub 2 miesiące testowali nieinwazyjne urządzenie TinniSoothe. Urządzenie to jest niewielkim modułem generującym dźwięk, zaprojektowanym tak, aby można było nosić je na

smyczy lub klipsie w ciągu dnia, a na noc umieszczać w stacji dokującej. Umożliwia ono użytkownikom dostosowanie częstotliwości dźwięku i jego głośności zgodnie z osobistymi preferencjami, a urządzenie podczas dokowania w nocy nadal emituje dźwięk. Uczestnicy zostali poproszeni o wypełnienie kwestionariusza do oceny szumów usznych, zdrowia psychicznego i fizycznego przed interwencją, po interwencji oraz po 2 miesiącach.

Wyniki: Wszyscy uczestnicy (20 weteranów, średnia wieku = 51,3, *SD* = 7,7, 80% mężczyzn) korzystali z urządzenia przez okres interwencji trwający 1 miesiąc, bez żadnych przypadków rezygnacji lub poważnych zdarzeń niepożądanych. Większość (75%) zdecydowała się zatrzymać urządzenie po upływie miesiąca, a 80% stwierdziło, że poleciłoby je znajomym i rodzinie. Po 2 miesiącach chęć dalszego korzystania z urządzenia zgłosiło tylko 13 uczestników. Od momentu rozpoczęcia badania do zakończenia interwencji i obserwacji uczestnicy zgłaszali znaczne zmniejszenie objawów szumów usznych. Chociaż ogólnie czas miał znaczący wpływ w przypadku zaburzeń snu, porównania parami nie wykazały znaczących zmian między poszczególnymi punktami czasowymi. Nie zaobserwowano znaczących różnic w pozostałych wynikach.

Wnioski: Badanie wykazało, że możliwość zastosowania urządzenie TinniSoothe oraz jego akceptowalność w leczeniu szumów usznych u weteranów wojskowych są ograniczone, choć istnieją pewne dowody potwierdzające jego skuteczność. Jednak po 2 miesiącach 65% uczestników nadal aktywnie korzystało z urządzenia, co wskazuje na konieczność przeprowadzenia dalszych badań nad jego skutecznością.

Słowa kluczowe: szumy uszne • technologie ubieralne • terapia dźwiękiem

Key to abbreviations	
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
GCSE	General Certificate of Secondary Education
GHQ-12	General Health Questionnaire-12
ISI	Insomnia Severity Index
NHS	National Health Service (UK)
Short form PCL-5	PTSD Checklist for DSM-IV short version
PHQ-15	Patient Health Questionnaire-15
PTSD	post-traumatic stress disorder
SWLS	Satisfaction with Life Scale
TFI	Tinnitus Functional Index
TRT	Tinnitus Retraining Therapy

Introduction

Tinnitus is the perception of noise without any external sound stimulation [1] and is most commonly associated with sound trauma, ageing, head injury, or damage to the ear structures [2]. Though there are inconsistencies in prevalence rates, tinnitus is more frequent in military veterans compared to the general population [3,4]. Tinnitus is often associated with loud noise exposure, which military personnel often experience during military service in addition to other hazards such as ototoxicity and trauma exposure [5]. Although the exact causes of tinnitus remain unclear, ample evidence highlights the profound impact of tinnitus on the lives of military personnel and veterans [6–8]. In service members and veterans, tinnitus has been associated with psychological difficulties including depression and anxiety, sleep difficulties, reduced job performance [6], and poorer general physical health [5]. Additionally, tinnitus treatment is estimated to cost the NHS approximately £750 million annually [9] and many individuals experience significant difficulties in accessing tinnitus treatment [10]. To our knowledge, there is no sound therapy intervention that offers a universally effective solution to tinnitus management [1,11–13] and many options are poorly researched [3,14]. Given the profound economic costs and barriers to treatment, the significant impact of tinnitus on the lives of military personnel and veterans, and the current lack of effective intervention, it is important to explore the feasibility of new interventions.

There are numerous tinnitus management strategies which include psychotherapies (e.g., cognitive behavioural therapy, acceptance and commitment therapy), sound-based interventions (e.g., Tinnitus Retraining Therapy – TRT), hearing devices (e.g., hearing aids and cochlear implants), neurofeedback and neuromodulation techniques, pharmacological and physical therapies, as well as emerging virtual and digital technologies (e.g., virtual reality) [15]. Expanding on sound therapy, a scoping review exploring various sound-based tinnitus interventions highlighted their potential in suppressing tinnitus symptoms [1]. Notably, this same review illuminated the need for further research evaluating the effectiveness of different sound therapy techniques [1].

Though there are differences in sound-based interventions, potential benefits include masking (i.e., reducing the perceived noise of the tinnitus), distraction (diverting one's attention away from the tinnitus), relaxation (stress reduction), sound enrichment (adding external sound to lessen the impact of tinnitus), and habituation (gradually reducing the perceptual salience of tinnitus) [16,17]. Sound interventions are widely used and generally well-accepted by patients, likely due to their simplicity and non-invasive nature [1]. Supporting their effectiveness, a network meta-analysis illustrated how sound stimulation alone performed better than medication alone, educational intervention alone, and no treatment [18]. Interestingly, combination therapy (e.g., sound stimulation and educational consultation) resulted in significantly better outcomes in reducing tinnitus symptoms in comparison to individual treatments [18].

Figure 1. TinniSoothe device worn around the neck during the day (**left**) and beside the bed at night (**right**). Photos courtesy TinniSoothe

There are various methods of sound-based tinnitus interventions such as TRT, which combines both sound stimulation with structured counselling to promote habituation [1,11]. Tinnitus Retraining Therapy involves structured counselling that is typically delivered over a period of 6 to 18 months [19]. The Habituation Theory [20] proposes that the negative interpretation of tinnitus leads to dysfunctional cognitive processing and distress. It proposes that to function effectively, the brain needs to select which stimulus to attend to and which to ignore. Thus, if the tinnitus is subjective, the development of tinnitus tolerance is the process of habituation. Interestingly, the US Department of Veterans affairs recommend a stepped-care model for tinnitus management, namely Progressive Tinnitus Management [21]. Similar to Tinnitus Retraining Therapy, Progressive Tinnitus Management integrates sound therapy with counselling and aims to reduce tinnitus-related distress. As both require counselling over multiple sessions, there is a need to explore potential sound-based interventions that do not require counselling.

The current project aims to explore the feasibility and acceptability of a non-invasive sound therapy, a wearable white-noise device that may be a promising alternative approach –Tinnisoothe [22]. This device is designed to deliver comfortable, discreet relief from tinnitus symptoms, and may offer more immediate support compared to other tinnitus interventions. This non-invasive device, shown in **Figure 1**, aims to reduce the perception of tinnitus and the attention directed towards it, thus providing relief [22]. TinniSoothe produces gentle, highly configurable white noise and can be used continuously for 24 hours without requiring anything in or around the ear. This device is a small module, designed to be worn on a lanyard or clip during the day and in a docking station at night, where it recharges while continuing to emit sound through its speaker, facilitating 24/7 use. The frequency and volume of the module can be adjusted according to personal preferences for daytime and nighttime use. The device is designed to combine two approaches: (a) distraction, by using external sounds to shift attention away from tinnitus, and (b) habituation, which gradually helps the brain reclassify tinnitus as an insignificant sound.

The device is patented with the UK Intellectual Property Office and is certified by the UK Medicines and Healthcare products Regulatory Authority, and may provide accessible and functional relief of tinnitus symptoms. To date, there has been no specific research into its feasibility or acceptability.

Material and methods

Participation in the current study was subject to providing written informed consent. The study was subject to approval by the University of Bath ethics committee (# 6783-10218).

Trial objectives and study design

The aim of the trial was to investigate the feasibility and acceptability of a non-invasive sound device for tinnitus in a sample of 20 UK military veterans. The device is called TinniSoothe [22]. The study was a single arm, within-participants exploratory design, taking place between November 2024 and July 2025. Recruitment for the trial took 16 days.

Sample size

This study was an acceptability, feasibility, and safety trial. Our target sample size of 20 allowed us to explore feasibility outcomes such as whether the sample can be recruited and participant retention. A power calculation was not justified as this was an acceptability and feasibility trial.

Recruitment

Participants were recruited through convenience sampling methods. This involved social media posts on LinkedIn, Facebook, and Instagram by Combat Stress, a national UK veterans mental health charity. The charity offers clinical mental health services to UK veterans.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	
1	Above the age of 18
2	Fluent in speaking and reading English
3	UK Armed Forces veteran
4	Persistent tinnitus for at least 3 months (participants had to confirm constant ringing or buzzing, bilateral or unilateral, lasting longer than 3 months)
5	Able to receive the device to their registered address
6	Able to follow study instructions
7	Sign the written consent form prior to any study-related procedures being performed
Exclusion criteria	
1	Below 18 years of age
2	Individuals who have already habituated to tinnitus, defined as those who report that their tinnitus is no longer bothersome or intrusive in daily life
3	Veterans receiving concurrent treatment for tinnitus (e.g., other wearable devices or ongoing audiological therapies)
4	Active self-harm or suicidal ideation
5	Severe psychotic disorder, dissociative identity disorder, or other severe mental health difficulty
6	Current alcohol or drug-use disorder or dependency requiring further support or treatment that would significantly impact treatment engagement
7	Unwilling and/or unable to provide informed consent

Screening and assessment

Interested participants completed a brief pre-screening questionnaire on SurveyMonkey that confirmed they had experienced tinnitus for at least 3 months. If an interested participant did not conform with the inclusion criteria at pre-screening, the veteran was thanked for their interest and given resources to support services. Eligible participants who met the pre-screening criteria were emailed the participant information sheet. As part of the consent procedure, participants were asked to accept a telephone call from the research assistant in which they were taken through the participant information sheet and given the opportunity to ask questions. During this call, the research assistant assessed and confirmed the participant's suitability based on their current goals. If the participant was eligible and interested, the participant was emailed a link to the baseline questionnaire via SurveyMonkey which included the consent form.

Inclusion and exclusion criteria

The initial screening questionnaire confirmed that veterans had experienced a constant ringing or buzzing (bilateral or unilateral) lasting longer than 3 months. The full inclusion and exclusion criteria are set out in **Table 1**.

Preparatory phase

The baseline survey incorporated questions assessing demographics (e.g., age, gender), in addition to the following measures: Tinnitus Functional Index (TFI) [23]; PTSD Checklist for DSM-IV Short Version (Short form PCL-5) [24]; Insomnia Severity Index (ISI) [25]; Patient Health Questionnaire-15 (PHQ-15) [26]; Satisfaction with Life Scale (SWLS) [27]; and the General Health Questionnaire-12 (GHQ-12) [28]. Additionally, hearing loss in each ear was assessed via a self-report question where participants were asked "If you are aware of your hearing loss and this has been assessed by an audiologist, at what level is your hearing loss in each ear? Please note: If you have not been assessed by an audiologist or are unsure, please tick 'Unsure.'" Participants were provided with guidance based on the British Society of Audiology definitions of hearing loss, with decibel hearing level ranges for each category as follows: Mild (21–40 dB), Moderate (41–70 dB), Severe (71–96 dB), and Profound (95+ dB). Participants were also asked if they have hearing aids and if so, in which ears.

After eligible participants completed the baseline questionnaire and consent form, the tinnitus device was sent to their address. This meant that the location of the feasibility trial was in the participant's usual environment. The package sent included: (a) the TinniSoothe module, (b) user instruction manual, (c) docking station, (d) lanyard, and (e) clothing pin. The research assistant scheduled a one-on-one phone call with each participant upon receiving the device, providing guidance on its setup and usage. The veteran was instructed to use the device for a period of 1 month (i.e., wear the device around their neck during the day and dock the device to the docking station at night). The research team was available throughout the trial period if any assistance was required.

Table 2. Measures administered at baseline, 1-month post-intervention, and 2-months follow-up

Measure	Baseline	1-month post-intervention questionnaire	2-month follow-up questionnaire
Demographics (e.g., age, sex, gender, employment status, military branch)	X		
TFI	X	X	X
Short form PCL-5	X	X	X
ISI	X	X	X
PHQ-15	X	X	X
SWLS	X	X	X
GHQ-12	X	X	X
Qualitative questionnaire assessing the TinniSoothe		X	

Note: X marks the time points when each questionnaire was sent to participants

Questionnaires

Participants were asked to complete a post-intervention questionnaire (i.e., 28 days post baseline) and a 2-month follow-up questionnaire. After completing the 28-day intervention period, veterans were given the option to keep or return the device. All participants, irrespective of device retention, were asked to complete the 2-month follow-up questionnaire in order to assess post-intervention outcomes following the 1-month exposure. While the 2-month follow-up provided information on continued device use, this was intended to observe patterns of engagement rather than assess longer-term effectiveness. Both questionnaires included the following measures: TFI [23], Short form PCL-5 [24], ISI [25], PHQ-15 [26], SWLS [27], and the GHQ-12 [28]. These questionnaires are listed in **Table 2** and outcome measures described below. Participants were asked to complete another questionnaire which comprised of qualitative questions assessing the device (e.g., the comfort level, how often they used the device etc.) at post-intervention. All instructions confirmed that the questionnaires were voluntary. All surveys were completed on SurveyMonkey, and participants were contacted via email asking them to complete the surveys. Consent was reaffirmed at all questionnaire timepoints via SurveyMonkey. Participants were able to withdraw data at any point up to 2 weeks after the final questionnaire was completed. From 2 weeks after the final survey, withdrawal was no longer possible due to data having then been anonymised.

Outcomes

An overview of the outcome measures collected throughout the study is set out in **Table 2**.

Feasibility

Feasibility was explored by assessing the ability to recruit the target sample of 20 participants (i.e., yes if the sample was recruited and no if it was not) and by participant retention (i.e., the proportion of participants who completed the study out of the total number of participants).

Acceptability

The device acceptability was assessed through the post-intervention qualitative questionnaire. This questionnaire included questions exploring participants' experience of the device (e.g., rating satisfaction of the usefulness of the device during the day and at night). Participants were asked whether they experienced any adverse effects and potential recommendations. Responses were a mixture of multiple choice and free text.

Primary Outcome Measure

TFI [23]: A 25-item measure assessing the severity and impact of tinnitus symptoms, with higher scores indicating greater tinnitus-related distress and functional impairment. Though the TFI includes 8 subscales, the present study only focused on the overall TFI score.

Secondary Outcome Measures

1. Short form PCL-5 [24]: A four-item measure assessing the presence of PTSD symptoms according to the DSM-IV criteria, with higher scores indicating greater symptom severity.
2. ISI [25]: A 7-item measure assessing current sleep difficulties, with higher scores indicating more severe insomnia symptoms.
3. PHQ-15 [26]: A 15-item measure assessing physical health and somatic symptoms, with higher scores indicating greater somatic symptoms.
4. SWLS [27]: A 5-item measure assessing life satisfaction, with higher scores indicating greater life satisfaction.
5. GHQ-12 [28]: A 12-item measure of potential mental health issues, primarily focusing on depression or anxiety, with higher scores indicating worse mental health. The GHQ-12 was assessed using a Likert scale (0, 1, 2, 3).

Statistical analyses

Analyses were conducted using RStudio version 4.4.3 (2025-02-28). The feasibility outcomes of the study were firstly reported as descriptive statistics. To assess the

Table 3. Sociodemographic characteristics of the sample ($n = 20$)

Variable	*n* (%)
Age	*M* = 51.3, *SD* = 7.7
Sex	
Male	16 (80%)
Female	4 (20%)
Education level	
School until 16 years / GCSE	3 (15%)
Further education (e.g., college, vocational training)	7 (35%)
Higher education (undergraduate degree)	5 (25%)
Master's degree	5 (25%)
Doctoral degree (PhD, MD, etc.)	
Ethnicity	
White British	20 (100%)
Employment status	
Employed full-time	11 (55%)
Employed part-time	2 (10%)
Self-employed/freelance	4 (20%)
Not working, looking after the home	1 (5%)
Not working, seeking employment	1 (5%)
Voluntary work	1 (5%)
Relationship status	
Married or living with a partner	15 (72%)
Single	2 (10%)
Divorced	2 (10%)
Widowed	1 (5%)
Military branch	
Army	12 (60%)
Royal Navy	6 (30%)
Royal Airforce	2 (10%)

primary and secondary outcomes of the study, scores at baseline were compared to the scores at 1-month post-intervention and at 2-month follow-up. Normality of each outcome measure at each timepoint was assessed using the Shapiro–Wilk test. For outcomes that met the normality assumption, repeated-measures ANOVA was conducted to evaluate changes across baseline, post-intervention, and follow-up. For outcomes that violated the normality assumption, the non-parametric Friedman test was used. Where the repeated-measures ANOVA indicated a significant main effect of time, pairwise comparisons were conducted with Bonferroni correction. For outcomes analysed with the Friedman test, post hoc pairwise comparisons using Wilcoxon signed-rank tests were performed when appropriate. All tests were performed at a significance level (α) of 0.05. All measures required complete item responses; thus, no item-level missing data were present. Participants who did not complete a questionnaire at a given timepoint were excluded from the corresponding repeated-measures analyses (complete-case analysis).

Results

Participants

Overall, 20 participants (mean age = 51.3; *SD* = 7.7) completed the study. The majority were male (80%) and had served in the army (60%); all participants were White British. The sample sociodemographic characteristics are presented in **Table 3**, and the specific hearing-related characteristics are shown in **Table 4**. All participants reported having experienced tinnitus for 12 months or more. None of the 20 participants who enrolled in the study dropped out of using TinniSoothe in the first month. At the end of the intervention period, 5 participants elected to return the device. There were 2 participants who were lost to the 2-month follow-up.

Table 4. Hearing characteristics of the sample ($n = 20$)

Variable	*n* (%)
Right hearing loss	
No	5 (25%)
Mild	2 (10%)
Moderate	4 (20%)
Unsure/have not been assessed by an audiologist	9 (45%)
Left hearing loss	
No	5 (25%)
Mild	3 (15%)
Moderate	4 (20%)
Unsure/have not been assessed by an audiologist	8 (40%)
Hearing aids	
Yes: both ears	6 (30%)
Yes: right ear (only)	2 (10%)
Yes: left ear (only)	0 (0%)
No	12 (60%)

Table 5. Device usability at 1-month post-intervention ($n = 20$)

Please answer the following by rating how satisfied/dissatisfied you were with the device in these different aspects	Dissatisfied/neutral *n* (%)	Satisfied *n* (%)
Usefulness of the device during the day	4 (20%)	16 (80%)
Usefulness of the device at night	11 (55%)	9 (45%)
Volume of the device	6 (30%)	14 (70%)
Weight of the device	0 (0%)	20 (100%)
Usability of the device	2 (10%)	18 (90%)
The process to set the device to your personal level	6 (30%)	14 (70%)
Instructions to use the device	1 (5%)	19 (95%)

At the 1-month post-intervention, 8 participants (40%) reported they used the device *most of the time* (20–23 hours per day), followed by *all of the time* (24/7 as instructed; 25%), *frequently* (16–19 hours per day; 20%), and *occasionally* (8–15 hours per day; 15%). At this timepoint, participants reported high satisfaction across multiple usability domains (**Table 5**). Satisfaction was highest for the weight of the device, with all participants rating it as *satisfied*. Similarly, 95% of participants reported being *satisfied* with the instructions for using the device, while 90% reported being *satisfied* with its usability. Notably, the usefulness of the device at night indicated more mixed feedback, with 55% reporting *some dissatisfaction/ neutral feelings,* and 45% expressing *satisfaction*. Other domains such as the process to set the device to your personal level and volume of the device indicated a broader spread but trended towards satisfaction, with the majority rating them as *satisfied*.

At 1-month post-intervention, 17 reported that others could hear the tinnitus device, and of those, 10 mentioned that others were bothered by it. The majority of participants (80%) reported that the tinnitus device did not help them return to activities, although there were 4 reports that the device did help. The majority of participants (80%) would recommend the device to friends and family. Additionally, most participants (90%) reported no adverse events. One participant reported a migraine, and another reported that they were more aware of their tinnitus because of the device. Of the 20 participants, 15 elected to keep using the device after the 1-month post-intervention period (5 elected to give the device back as they did not wish to continue using it). At the 2-month follow-up, 18 participants completed the questionnaire, even though 5 of them had elected to return the device after completion of the 28-day intervention period and therefore had not used it during the second month. Among the 13 who retained the device, usage

Table 6. Outcomes at baseline, 1-month post-intervention ($n = 20$, third column), and 2-month follow-up ($n = 18$, final column). Note that in the final column, 5 participants had already returned the device and thus did not use it during the second month; these 5 were retained in the analysis to reflect post-intervention outcomes following the initial intervention, which was the primary aim of the study

Variable	Baseline *M* (*SD*)	1-month post-intervention *M* (*SD*)	2-month follow-up *M* (*SD*)
TFI	58.72 (13.87)	45.66 (17.51)	40.51 (16.38)
Short form PCL-5	2.85 (3.01)	3.00 (3.32)	3.22 (3.45)
ISI	13.15 (5.00)	10.85 (5.82)	9.17 (6.46)
PHQ-15	6.75 (4.33)	6.45 (4.94)	5.83 (4.67)
SWLS	22.35 (6.67)	22.35 (8.13)	23.94 (7.53)
GHQ-12	13.75 (6.09)	11.35 (5.54)	11.22 (6.21)

during the follow-up varied: 3 used it *all of the time* (24/7 as instructed), 1 *most of the time* (20–23 hours per day), 3 *frequently* (16–19 hours per day), 3 *occasionally* (8–15 hours per day), and 3 used it *rarely* (1–7 hours per day). Two participants were lost to follow-up.

The mean changes for each of the primary outcomes are presented in **Table 6**. As the TFI and ISI scores met the assumption of normality, repeated-measures ANOVAs were conducted. For measures that violated the assumption of normality, including the SWLS, PHQ-15, GHQ-12, and the Short form PCL-5, the non-parametric Friedman test was used to compare scores across timepoints. Participants showed significant improvements in tinnitus symptoms (TFI) across the three time points, as indicated by a repeated-measures ANOVA (sphericity violated, Greenhouse–Geisser corrected), $F = 9.37$, $p = 0.003$. Post hoc paired *t*-tests with Bonferroni correction revealed that TFI scores decreased significantly from baseline to post-intervention ($p = 0.020$) and from baseline to 2-month follow-up ($p = 0.014$), with no significant change between post-intervention and follow-up ($p = 0.303$). Participants showed a significant overall effect of time on sleep disturbances (ISI) across the three time points, as indicated by a repeated-measures ANOVA (sphericity violated, Greenhouse–Geisser corrected, $F = 5.24$, $p = 0.020$). However, post hoc paired *t*-tests with Bonferroni correction revealed no statistically significant changes between neighbouring time points. No significant changes were observed across time in life satisfaction (SWLS; $\chi^2 = 2.58$, $p = 0.276$), somatic symptoms (PHQ-15; $\chi^2 = 0.95$, $p = 0.621$), general mental health difficulties (GHQ-12; $\chi^2 = 4.03$, $p = 0.133$), or post-traumatic stress symptoms (Short form PCL-5; $\chi^2 = 1.68$, $p = 0.431$).

Discussion

This study has explored the feasibility and acceptability of a new non-invasive sound therapy white noise device. There appeared to be evidence of acceptability and feasibility with all participants using the device for the 1-month period, with no dropouts or serious adverse events (two minor adverse events). Additionally, 15 participants (75%) elected to continue using the device after the 1-month trial ended and 16 participants (80%) reported they would recommend the device to friends and family. On the other hand, long-term usage of the device is unknown, with just 13 of the 20 participants continuing beyond the first month (5 gave it back and 2 were lost to follow-up); 3 of those 13 said they used the device rarely (1–7 hours per day). That is, at the final point of contact, there were just 13 active users remaining out of the original 20, so further investigation of efficacy is needed.

This study addresses a key gap by exploring the feasibility and acceptability of a non-invasive sound therapy device in a UK veteran population. Prior research involving trauma-focused treatment trials for military personnel and veterans highlights how treatment dropout is often higher than in trials among the general population [29,30]. Though the current sample was not trauma-focused, a veteran sample may have predicted similar attrition. Veterans may dropout for various reasons such as work conflicts, perceived treatment ineffectiveness, concerns with confidentiality, and stigma-related concerns [30]. However, all participants completed the one-month intervention period with no dropouts. This highlights the feasibility and acceptability of this non-invasive device in this population. Since there were no serious adverse events reported, this illustrates how this non-invasive device is unlikely to cause harm. At the 2-month follow-up, continued use of the device declined relative to the intervention period. There were 5 participants who elected to return the device at the end of the 28-day intervention and 2 were lost to follow-up, leaving 13 remaining active users.

While the overall satisfaction for the device was high, limitations of the device should be noted. Firstly, the usefulness of the device at night received relatively mixed feedback, with 55% of participants reporting dissatisfaction. Further, some participants reported the device could be heard by others, and in 59% of these participants, this caused some disturbance, indicating a potential limitation of this device in social environments. As such, though the device was generally acceptable, improvements in night-time functionality and sound masking may enhance its adoption.

Nonetheless, the results suggest tentative evidence of efficacy with respect to the primary outcome and potential secondary outcomes. Specifically, participants showed

statistically significant improvements in tinnitus symptoms across the three time points, with scores significantly improving from baseline to post-intervention and from baseline to follow-up.

For sleep disturbances, although there was a significant overall effect of time, pairwise comparisons between timepoints were not statistically significant. This improvement may reflect the proposed mechanism of action, whereby the non-invasive device attempts to facilitate both distraction and habituation. By introducing a consistent white noise sound, participants may have experienced reduced attentional focus on the tinnitus and thus a gradual reduction in tinnitus salience. While the data suggests potential improvements in outcomes, since there is no comparator group in the current study, results should be interpreted with caution and seen as tentative evidence on the potential effectiveness of the device.

Interestingly, prior research has indicated the benefit of sound therapy in suppressing tinnitus symptoms [1,18,31–33] and thus, further research is needed to explore the effectiveness of the TinniSoothe device. Additionally, there is currently limited consensus on the effectiveness of sound therapy in tinnitus management [34], further highlighting the need for more research.

In respect to the remaining secondary outcomes, the results indicated no significant change. This is unsurprising, given that the non-invasive device aims to reduce symptoms of tinnitus rather than targeting secondary outcomes. Notably, as participants reported varying levels of device use during the month following the intervention, follow-up findings should be interpreted with caution. It was outside the scope of this feasibility trial to explore the matter further. Additionally, the above findings should be interpreted cautiously as the design of the study (no comparator group) means that the efficacy of the device could not be assessed.

Limitations

The study included male and female veterans and implemented a range of questionnaires to assess both their experiences using the device and their mental health and wellbeing outcomes, providing comprehensive insight into their perspectives. However, there were several limitations. Firstly, the convenience sample recruitment method could potentially introduce biases as it was not randomly selected. Given the small number of veterans, the representativeness is limited which may restrict the generalisability to the broader veteran population. Further, as it was out of the scope of the study to include a comparator group, the findings do not provide insight into the effectiveness of this device. Additionally, the study did not include a screening measure to rule out tinnitus arising from temporary or secondary causes (e.g., ear infection, impacted cerumen), which may have reduced the consistency of the sample, although all participants reported experiencing tinnitus for 12 months or longer. Nonetheless, future research should incorporate screening questions to ensure tinnitus is not attributable to reversible or identifiable factors. Additionally, while all participants who completed the 2-month follow-up questionnaire ($n = 18$) were included in the analysis, 5 had returned the device after the 1-month intervention and therefore reported no device use during the follow-up period. This will affect interpretation of outcomes beyond the primary intervention period. Finally, future research should recruit a larger sample and incorporate a comparator group to explore the effectiveness of this device over a longer time-frame.

Conclusions

This study presents evidence that TinniSoothe offers a broadly acceptable, feasible, and safe intervention for tinnitus management. Patients who used the non-invasive device for 1 month reported a significant reduction in tinnitus symptoms from baseline to post-intervention and from baseline to 2-month follow-up. However, with 13 of the 20 participants reporting continued device use at the 2-month follow-up, variability in sustained engagement highlights differences in user adherence after the intervention period. A larger randomised study exploring the effectiveness of this device is necessary to explore whether TinniSoothe can be recommended.

Ethics and dissemination

Participation was subject to providing written informed consent. The study was subject to approval by the University of Bath ethics committee (#6783-10218). Throughout the trial, participants personal information was password protected, with access limited to the Combat Stress study team. Participants were allocated a unique ID, with all data stored and references made to this ID. All personally identifiable information was only seen by the Combat Stress research team and data was anonymised prior to analysis.

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Competing interests

The authors declare they have no competing interests.

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WIDEBAND ACOUSTIC IMMITTANCE (WAI) AND HISTOPATHOLOGY IN A MOUSE MODEL OF OTITIS MEDIA

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Abstract

Introduction: This study aimed to: (1) quantify and compare middle ear status in two mice strains, C57BL/6J and CBA/CaJ, using wideband acoustic immittance (WAI) to measure wideband absorbance at ambient pressure (WBA) and at tympanometric peak pressures (WBT); (2) determine the percentage of mice with histologic evidence of otitis media (OM) after nasal inoculations with *Bordetella hinzii*; (3) assess how *B. hinzii* affects WBA and WBT; and (4) evaluate if antibiotic treatment reduces OM and restores absorbance to normal.

Material and methods: Eight C57BL/6J and eight CBA/CaJ mice were used in Experiment 1. WBA and WBT (averaged across 0.5–8 kHz) were measured at baseline and 3 and 6 weeks after *B. hinzii* inoculation. Middle ear histopathology was performed to confirm the presence of OM. In Experiment 2, ten C57BL/6J mice with OM received antibiotics, and absorbance was tracked at baseline, during OM, and post-treatment.

Results: (1) Baseline absorbance responses were reliably measured in both strains and both showed similar results with peak WBA (~0.4) near 1 kHz and maximal WBT at –50 daPa near 6–8 kHz; (2) None of the CBA/CaJ developed OM, whereas 13 of 16 C57BL/6J ears showed OM histologically; (3) WBA and WBT remained normal in CBA/CaJ mice post-inoculation. In C57BL/6J mice, WBA at ambient pressure was insensitive to OM, but WBT was significantly reduced at 3 and 6 weeks post-inoculation ($p = 0.001$); (4) Antibiotic-treated C57BL/6J mice showed WBT recovery as OM resolved histologically.

Conclusions: Wideband acoustic immittance provides reliable absorbance measures in mice. C57BL/6J mice are susceptible to OM induced by *B. hinzii*, whereas CBA/CaJ are resistant. WBT can be used to detect and monitor OM in mice. Limitations of the study include a modest sample size and relative rather than absolute values of WBA and WBT due to species differences in calibration.

Keywords: otitis media • histopathology • antibiotics • mouse model • wideband tympanometry • *B. hinzii*

SZEROKOPASMOWA IMPEDANCJA AKUSTYCZNA (WAI) I HISTOPATOLOGIA W MYSIM MODELU ZAPALENIA UCHA ŚRODKOWEGO

Streszczenie

Wprowadzenie: Celem niniejszego badania było: 1) ilościowe określenie i porównanie stanu ucha środkowego u dwóch szczepów myszy (C57BL/6J i CBA/CaJ) z wykorzystaniem szerokopasmowej impedancji akustycznej (WAI) do pomiaru szerokopasmowej absorbancji w naturalnych warunkach ciśnienia atmosferycznego (WBA) i przy ciśnieniu szczytowym (WBT); 2) określenie odsetka myszy objawami zapalenia ucha środkowego (OM), stwierdzonego w badaniu histologicznym, po donosowym podaniu bakterii *Bordetella hinzii*; 3) ocena wpływu *B. hinzii* na WBA i WBT; oraz 4) ocena, czy leczenie antybiotykami zmniejsza OM i przywraca absorbancję do normy.

Materiał i metody: W eksperymencie 1. wykorzystano osiem myszy C57BL/6J i osiem myszy CBA/CaJ. WBA i WBT (średnia dla zakresu 0,5–8 kHz) zmierzono w stanie wyjściowym oraz 3 i 6 tygodni po zaszczepieniu *B. hinzii*. W celu potwierdzenia OM wykonano histopatologię tkanek ucha środkowego. W eksperymencie 2. dziesięć myszy C57BL/6J z OM otrzymało antybiotyki, a absorbancję zmierzono: w stanie wyjściowym, podczas OM i po leczeniu.

Wyniki: 1) Uzyskano wiarygodne pomiary absorbancji u obu szczepów myszy, a wyniki były zbliżone: dla szczytu WBA (~0,4) przy 1 kHz oraz maksymalny WBT przy –50 daPa w zakresie 6–8 kHz; 2) u żadnej z myszy CBA/CaJ nie stwierdzono rozwoju zapalenia ucha środkowego, podczas gdy w 13 z 16 uszu myszy C57BL/6J stwierdzono OM w badaniu histologicznym; 3) WBA i WBT pozostały prawidłowe u myszy CBA/CaJ po inokulacji. Wartości WBA u myszy C57BL/6J przy ciśnieniu wyjściowym pozostawały podobne niezależnie od tego, czy ucho

było zdrowe, czy wykazujące OM, natomiast WBT w przypadku OM uległo istotnemu obniżeniu w 3. i 6. tygodniu po inokulacji ($p = 0{,}001$); 4) u myszy C57BL/6J leczonych antybiotykami wartości WBT wracały do normy równolegle z ustępowaniem zmian histopatologicznych OM.

Wnioski: Szerokopasmowa impedancja akustyczna zapewnia wiarygodny pomiar absorbancji u myszy. Szczep C57BL/6J myszy jest podatny na rozwój zapalenia ucha środkowego wywołanego przez *B. hinzii*, podczas gdy CBA/CaAJ jest odporny. WBT może być stosowane do wykrywania i monitorowania OM u myszy. Do ograniczeń niniejszego badania należą: niewielka liczebność próby oraz wykorzystanie wartości względnych, a nie bezwzględnych WBA i WBT, które to wartości wynikają z różnic gatunkowych w kalibracji.

Słowa kluczowe: zapalenie ucha • histopatologia • antybiotyki • model mysi • tympanometria szerokopasmowa • *B. hinzii*

Key to abbreviations	
3D	three-dimensional
ABR	auditory brainstem response
AOM	acute otitis media
CO	cochlea
DPOAE	distortion product otoacoustic emission
EAC	external auditory canal
EDTA	ethylenediaminetetraacetic acid
IP	intraperitoneal
ME	middle ear
OM	otitis media
OME	otitis media with effusion
SMTP	sulfamethoxazole and trimethoprim
SNR	signal to noise ratio
WAI	wideband acoustic immittance
WBA	wideband absorbance
WBT	wideband tympanometry

Introduction

Two-thirds of children experience at least one episode of acute otitis media (AOM) by the age of 5 [1], with some children prone to recurrent or chronic OM [2]. Chronic OM may lead to a permanent conductive or mixed hearing loss as a result of chronic inflammation and hyperplasia of middle ear mucosa and breakdown of its epithelial lining [2–4]. For OM to develop, the pathogens must adhere to the nasopharyngeal epithelium, enter the middle ear cavity intranasally or through the Eustachian tube, and overcome the immune and other natural defense mechanisms of the middle ear [5,6].

Many species have been used to investigate OM and changes in middle ear status following inoculation with experimental bacteria [7–15]. Mice provide many advantages for OM research including low cost, ease of care, availability of inbred and mutant strains that could provide insights on the genetics of OM relevant to humans [1,13]. Standard tympanometry performed on 61 inbred mouse strains [16] revealed 46 with normal type A tympanograms, 3 with type B, flat tympanograms, 3 with type C tympanograms with a negative middle ear peak pressure, and 9 unclassified. Mcph1-deficient mice, a model of microcephaly, spontaneously developed OM that increased in frequency and severity with age [17].

The etiology of acute and chronic OM has been investigated with different pathogens, treatments and diagnostic tools [13,18–20]. Using otomicroscopy, BALB/c mice were found to be much more susceptible to bacteria-induced OM than C57BL/6J and Swiss-Webster mice [14]. After inducing OM in C57BL/6J mice with *Bordetella pseudohinzii*, auditory brainstem response (ABR) thresholds increased and distortion product otoacoustic emission (DPOAE) amplitudes decreased across a broad range of frequencies [9]; however, these functional metrics failed to distinguish middle ear dysfunction from cochlear hearing loss that can rapidly develop in some strains [21,22].

Sound transmission from the middle ear to the cochlea is frequency dependent, varies across species, and can be disrupted by middle ear pathologies [23–25]. In contrast to traditional tympanometric measurements typically performed at a single frequency (adults, 226 Hz; children, 1000 Hz), wideband acoustic immittance (WAI) provides measurements of (a) wideband absorbance at ambient pressure (WBA) that assesses the proportion of sound energy absorbed into the middle ear across a wide frequency range (0.25–8 kHz) at ambient pressure, and (b) wideband tympanometry (WBT) that measures energy absorbance at various ear canal pressures, similar to traditional tympanometry, but across a wide frequency range (0.25–8 kHz). In contrast to traditional methods performed at a single frequency, WAI is highly effective for assessing middle ear function over a broad frequency range by computing the power absorbed by the middle ear relative to the incident power from 0.25 to 8 kHz [26,27]. Acoustic power absorbance values, which range from 1.0 (100%) to 0.0 (0%), have proved useful in assessing middle ear pathologies such as otosclerosis, ossicular discontinuity, OM with effusion, and tympanic membrane perforation in humans [28–30]. However, additional research is needed in both humans and animals to develop norms and detect various dysfunctions [31]. WAI was used to study OM in chinchillas inoculated with non-typeable *Haemophilus* influenza [11]. Reduced absorbance at 4 days post-inoculation was attributed mainly to buildup of middle ear pressure whereas reduced absorbance at 8 days post-inoculation was attributed to OM with effusion and structural changes in the middle ear; however, these results were not confirmed histologically [32]. Because the full resolution of OM can occur over several weeks or more, further changes in absorbance would likely have been missed [13]. Although WAI is well established in human research, this study is innovative in its application of WAI to a mouse model of otitis media, incorporating longitudinal monitoring and pressure manipulation.

Table 1. Summary of the histology results including: tissue ID, strain of mouse, survival time (in weeks) post inoculation of *B. hinzii* and the status of the middle ear cavity. Results shows 13 of the 16 ears of all C57BL/J6 strains ($n = 8$) got infected, whereas none of the CBA/CaJ got infected with *B. hinzii*

Tissue ID	Strain	Survival time post inoculation [weeks]	Status of middle ear cavity
11WB03	C57BL/6J	3	Severe bilateral OM
11WB04	C57BL/6J	3	Moderate unilateral OM
11WB05	C57BL/6J	3	Severe bilateral OM
11WB06	C57BL/6J	3	Severe bilateral OM
11WB07	C57BL/6J	6	Clear
11WB08	C57BL/6J	6	Severe bilateral OM
11WB09	C57BL/6J	6	Severe bilateral OM
11WB10	C57BL/6J	6	Severe bilateral OM
11WB13	CBA/CaJ	6	Clear
11WB14	CBA/CaJ	6	Clear
11WB15	CBA/CaJ	6	Clear
11WB16	CBA/CaJ	6	Clear
11WB17	CBA/CaJ	3	Clear
11WB18	CBA/CaJ	3	Clear
11WB19	CBA/CaJ	3	Clear
11WB20	CBA/CaJ	3	Clear

WAI could be extremely useful for identifying middle ear dysfunction in murine models of human disorders such as Downs syndrome [33], genes that contribute to the development of OM [16], and assessing the development and resolution of OM and antibiotic treatment. In Experiment 1, we tested for differences in the development of OM between two widely used murine strains, C57BL/6J and CBA/CaJ mice, by inoculating them with *B. hinzii*, a human pathogen associated with OM. WAI was conducted pre- and post-inoculation and WBA and WBT were measured to compare the frequency- and tympanometric pressure-dependent changes in absorbance caused by OM in these two strains. OM was confirmed by histological assessment of the middle ear. In Experiment 2, C57BL/6J mice with OM induced by *B. hinzii* received a 4-week course of oral combination antibiotic treatment (sulfamethoxazole and trimethoprim) often used to treat bacterial middle ear infections in humans [34]. Following antibiotic treatment, the mice were evaluated by WBT and histology to assess the resolution of OM.

Material and methods

Experiment 1: WAI and histology pre/post *B. hinzii* inoculation

Animals

Eight male CBA/CaJ mice and eight male C57BL/6J mice (Jackson Laboratories, Bar Harbor, ME) were used in Experiment 1. The 16 mice (8 per strain) were inoculated with *B. hinzii*. **Table 1** shows the strains, timeline of sacrifice, and status of the middle ear cavity based on histological examination at time of sacrifice (see Results). Mice were 6 weeks of age at the start of the study and were housed in groups of 3 or 4 in autoclaved, static micro-isolator cages with food and water available *ad lib*. Irradiated gel packs (Hydrogel, Clear H_2O, Portland, ME) were used as water source to avoid potential cross-contamination between cages. Ambient temperature and relative humidity were maintained at 21–22°C and 55–60% respectively and a 12 : 12 light : dark cycle.

B. hinzii preparation

The two experimental groups ($n = 8$ per strain) were bi-nasally inoculated with 25 µL of a suspension of 2.45×10^3 cfu/mL of *B. hinzii* (isolated and characterized from a spontaneous occurrence within our animal facility) [15]. The isolate was maintained in tryptic soy broth with 5% glycerol and stored at –80°C. Inoculation medium was prepared by culturing bacteria on 5% sheep blood agar for 24 h at 37°C. Bacteria were then collected with a sterile swab and suspended in sterile phosphate buffered saline to the desired concentration.

WAI at both ambient pressure (WBA) and tympanometric pressure (WBT)

The Interacoustics wideband tympanometry system (research version 3.2.1) with Interacoustics probe assembly was used in this study. The equipment was calibrated

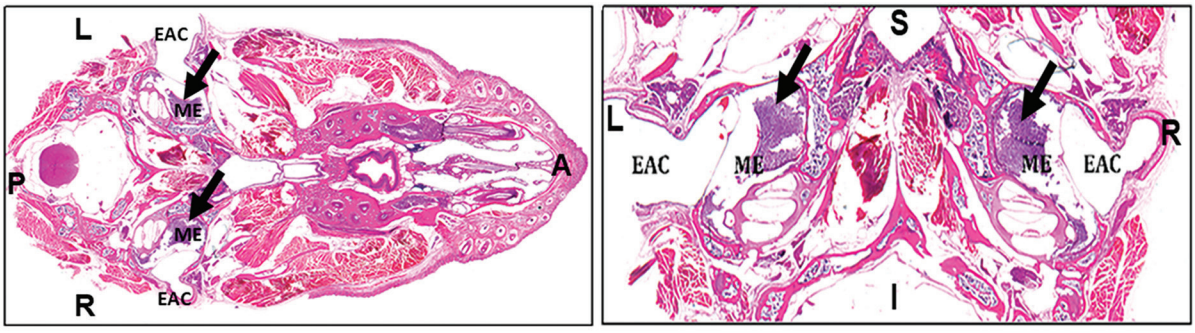

Figure 1. Standard histological preparation used in the present study. Upper panel shows a horizontal whole head section from a *B. hinzii*-exposed mouse; the temporal bone region is enlarged in the lower panel. In this bilaterally affected sample, note the accumulation of inflammatory exudate (black arrows) in the middle ear space (ME) and lack of exudate in the external auditory canal (EAC). Eustachian tubes, not shown in this section, were also always free of inflammation. All infected ears were graded as moderate or severe regardless of post-inoculation interval, consistent with the chronic nature of OM. Middle ear space (ME), external auditory canal (EAC), cochlea (CO), L (left), R (right), S (superior), I (inferior), A (anterior), and P (posterior)

according to the manufacturer's specification and a daily verification procedure was performed to ensure probe integrity and stimulus accuracy. In the absence of mouse species-specific calibration and given its smaller ear canal, we employed the 'newborn' calibration setting as a practical approximation [35]. Calibration was conducted by using the two tubes of the two sets of calibration tubes (Reflwin Interacoustics) at the beginning of each test day. Once successful tube calibration was obtained, WBA and WBT measurements were obtained from both ears of each mouse. Thirty-two click responses were acquired and valid sweeps averaged and analyzed.

All measurements were obtained from mice that had been lightly anesthetized in an isoflurane by chamber induction. Testing was completed in a quiet laboratory setting to minimize external noise. During absorbance testing, the anesthetized mouse was placed in the prone position on a flat surface. A sterilized probe ear tip, with a flanged flexible 3–5 mm diameter eartip was securely placed in the mouse ear canal (with practice, the investigators became adept at probe placement). Absorbance measures were obtained from both ears in response to clicks as pressure was slowly swept from +200 daPa to –300 daPa at a slow pump speed of 100 daPa/sec. The responses to the 32 click stimuli were recorded across 1/8 octave bands from 0.25 to 8 kHz, yielding 31 data points. Of the 31 recorded data points in the spectral analysis, 26 frequencies were analyzed; the six lowest frequencies (0.25–0.45 kHz) were excluded due to extremely low absorbance, possibly caused by the high stiffness of the mouse middle ear at low frequencies [36], and/or minor changes in the ear-probe calibration. Absorbance was measured five times during each test and the average was calculated. To ensure measurement reliability, the probe was removed and repositioned between recordings. WAI is an objective assessment of middle-ear status; however, the examiner was blinded to the experimental condition of each animal during data collection.

Histopathology

Mice were sacrificed either 3 weeks (half the mice) or 6 weeks (other half) post-inoculation. Mice were sacrificed with an overdose of pentobarbital (200 mg/mL, IP) and transcardially perfused with 45 mL of fixative containing 4% paraformaldehyde and 0.1% glutaraldehyde in Sorensen's phosphate buffer. Following perfusion, the lower jaw and scalp were removed, and the head immersed in fixative for several days. Heads were then rinsed free of fixative and placed in 14% acid free ethylenediaminetetraacetic acid (EDTA) for decalcification at 4°C for 2 weeks. Tissues were processed and embedded in paraffin and sectioned in the horizontal plane at a thickness of 4 µm. Ten sequential sections were saved at 100 µm intervals throughout the ventral–dorsal aspect of the middle ear space. Sections were stained with hematoxylin and eosin and cover slipped with Permount. All tissues were examined under an Olympus BH-2 upright light microscope for evidence of infection (inflammatory cells, bacterial biofilm, and debris) in both left and right middle ear spaces, external auditory canals, and Eustachian tubes, as well as the nasopharynx and sinus spaces. Histologically, the incidence of OM (present or absent) was classified as clear, unilateral, or bilateral. Earlier pilot studies had attempted to grade severity of the infection using a semi-quantitative scale (0–4) but showed infections to be robust or absent. For that reason, efforts to grade severity were not used in the present study.

Statistical analyses of Experiment 1

Test–retest reliability of baseline WBA as a function of frequency (0.5–8 kHz) and average WBT as a function of tympanometric pressure were analyzed to assess intra-session reliability and consistency of the five runs of each mouse strain using independent sample *t*-tests, and results were considered significantly different when Cohen's $d < 0.05$. Paired samples *t*-tests of the baseline WBA were conducted to test the mean differences between the right and left ears of each mouse strain. If results were not significantly different, data from both ears were averaged. Absorbance data were summarized as means and standard deviations.

Data analyses using parametric tests included both within- and between-mouse strain comparisons to identify differences in mean WBA versus frequency (0.5, 1, 2, 4, 6, 7, and 8 kHz) and mean WBT absorbance (averaged over 0.5 to

Table 2. Test–retest reliability between the five runs of baseline wideband absorbance at ambient pressure (WBA) in each of the C57 ($n = 8$) and CBA mice ($n = 8$). Results showed no significant differences between the five runs in both mouse strains at baseline

Frequency [kHz]	Mouse strain	Cronbach's α	95% CI Lower bound	95% CI Upper bound
0.5	C57	0.785	0.708	0.846
	CBA	0.729	0.636	0.803
1	C57	0.760	0.706	0.809
	CBA	0.717	0.610	0.800
2	C57	0.819	0.784	0.851
	CBA	0.801	0.734	0.855
4	C57	0.712	0.696	0.734
	CBA	0.839	0.813	0.865
6	C57	0.778	0.710	0.833
	CBA	0.839	0.813	0.865
7	C57	0.762	0.649	0.734
	CBA	0.805	0.754	0.849
8	C57	0.748	0.656	0.819
	CBA	0.809	0.762	0.851

8 kHz frequencies) at five tympanometric pressures (–200, –100, 0, +100, and +200 daPa) at baseline, 3 weeks post-inoculation, and 6 weeks post-inoculation. Within and between-strain comparisons were conducted using a series of one-way repeated measures ANOVA at three time points. If a main effect was significant, Bonferroni *post hoc* testing was performed with significance of $p < 0.05$.

Experiment 2: Recovery of WBA after antibiotics

For Experiment 2, 10 male C57BL/6J mice infected with *B. hinzii* were used to test the recovery of WBA and WBT absorbance following treatment of OM with antibiotics. The ten C57BL/6J mice were 6 weeks old at the onset of testing. Mice, lightly anesthetized with isoflurane, were inoculated intranasally with 25 μL of 1.95×10^4 cfu/mL suspension of *B. hinzii* and subsequently allowed to recover in their home cage. Four weeks after inoculation, a time sufficient to allow for development of OME, all mice were placed on a 4-week course of sulfamethoxazole (320 mg/L) and trimethoprim (64 mg/L) oral antibiotic suspension. Serial WBA and WBT absorbance measurements were conducted at baseline, after inoculation of *B. hinzii*, and following a 4-week antibiotic treatment to test for recovery of normal middle ear status.

Statistical analyses of Experiment 2

Recovery of absorbance was assessed in 10 C57BL/6J mice infected with *B. hinzii* following antibiotics treatment. Descriptive statistics were used to show the temporal changes in the WBT profiles measured at baseline, 1 week, and 4 weeks post-inoculation and then after 1 month of continuous antibiotic treatment (4 weeks post-antibiotic). To assess the recovery of absorbance following antibiotic treatment, a one-way repeated-measures, within-subject ANOVA was conducted, followed by multiple comparisons against the baseline values of the ten C57BL/6J mice infected with *B. hinzii*. Statistically significant differences were considered at a $p < 0.05$. All parametric statistical analyses were conducted using JASP software (version 0.18.3).

Ethical approval

All aspects of the care and use of these rodents in Experiment 1 and 2 were carried out in accordance with the Care and Use of Laboratory Animals of the National Institutes of Health, and the study protocol was approved by the Washington University in St. Louis, Missouri Animal Studies Committee (Protocol No. 20090049).

Results

Experiment 1: Histology and WBA pre/post *B. hinzii*

Histological phenotype

Histological examination of tissues from *B. hinzii* inoculated mice revealed inflammatory cells, acellular matrices, and bacterial biofilms localized to the middle ear. Although the suspension of *B. hinzii* was inoculated through the nasal cavity, the infection was limited to the middle ear cavity. **Table 1** illustrates the status of the middle ear cavity categorized by strain, group, and time of sacrifice. As shown in **Table 1** and **Figure 1**, histological examination of the eight C57BL/6J mice showed that 7 of 8 mice had

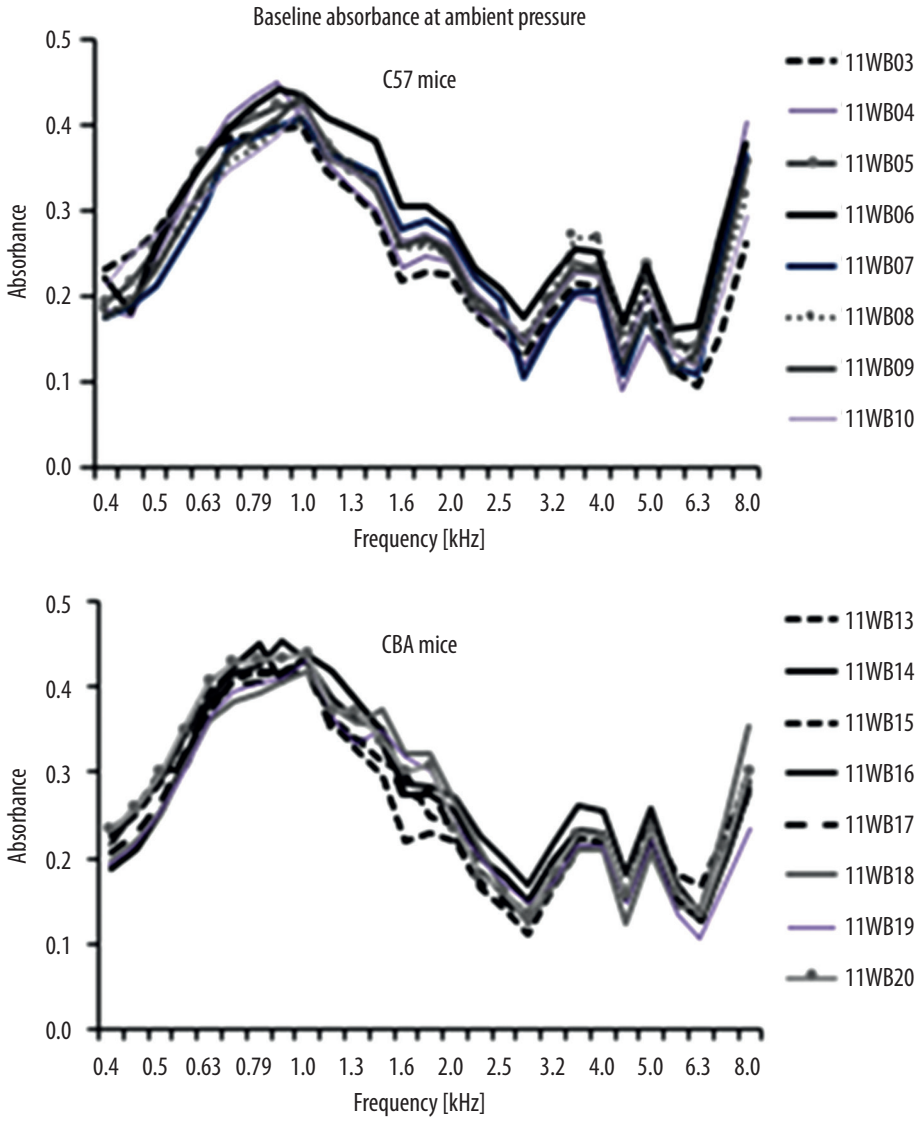

Figure 2. Baseline wideband absorbance versus frequency measured at ambient pressure (WBA). Mean data from both ears of each of the eight C57BL/6J mice (top panel) and each of the eight CBA/CaJ mice (bottom, $n = 8$). Both strains exhibited similar absorbance values with the highest peak around 1 kHz, a second peak near 8 kHz, and a characteristic M-shape absorbance profile between 2.8 and 6.3 kHz. The absorbance profiles within and between strains are similar, suggesting similar probe placement and middle ear properties in both strains

positive histology for OM. These seven C57BL/6J mice developed severe OM bilaterally ($n = 6$, 12 ears) and a moderate OM unilaterally ($n = 1$, 1 ear of 11WB04 mouse). Only one inoculated C57BL/6J mouse (11WB07) failed to develop signs of OM in either ear. Among the OM positive mice (**Figure 1**), infection was limited to the middle ear, causing acute and chronic suppurative OM (black arrows), without affecting the ear canal or inner ear. In contrast, none of the eight CBA/CaJ mice ($n = 8$, 16 ears) showed signs of OM in either ear at either 3 weeks or 6 weeks post inoculation, indicating that they were resistant to *B. hinzii* infection.

WBA post-inoculation

Based on histological findings of 16 C57BL/6J ears, 13 ears developed AOM bilaterally. Only three ears of two mice (two ears of 11WB07 and the left ear of 11WB4) were clear of infection; therefore, data from these three ears were not included in the analysis. **Table 2** shows the results of the test–retest reliability of the five WBA runs of each C57BL/6J and CBA/CaJ mouse. Cronbach's α correlation agreement was good to strong (0.712–0.839), with minimal variability between the confidence limits among the five WBAs recorded in each animal of the C57BL/6J and CBA/CaJ mice, suggesting stability of the recorded absorbance. Paired-samples *t*-test analysis of the baseline WBA from

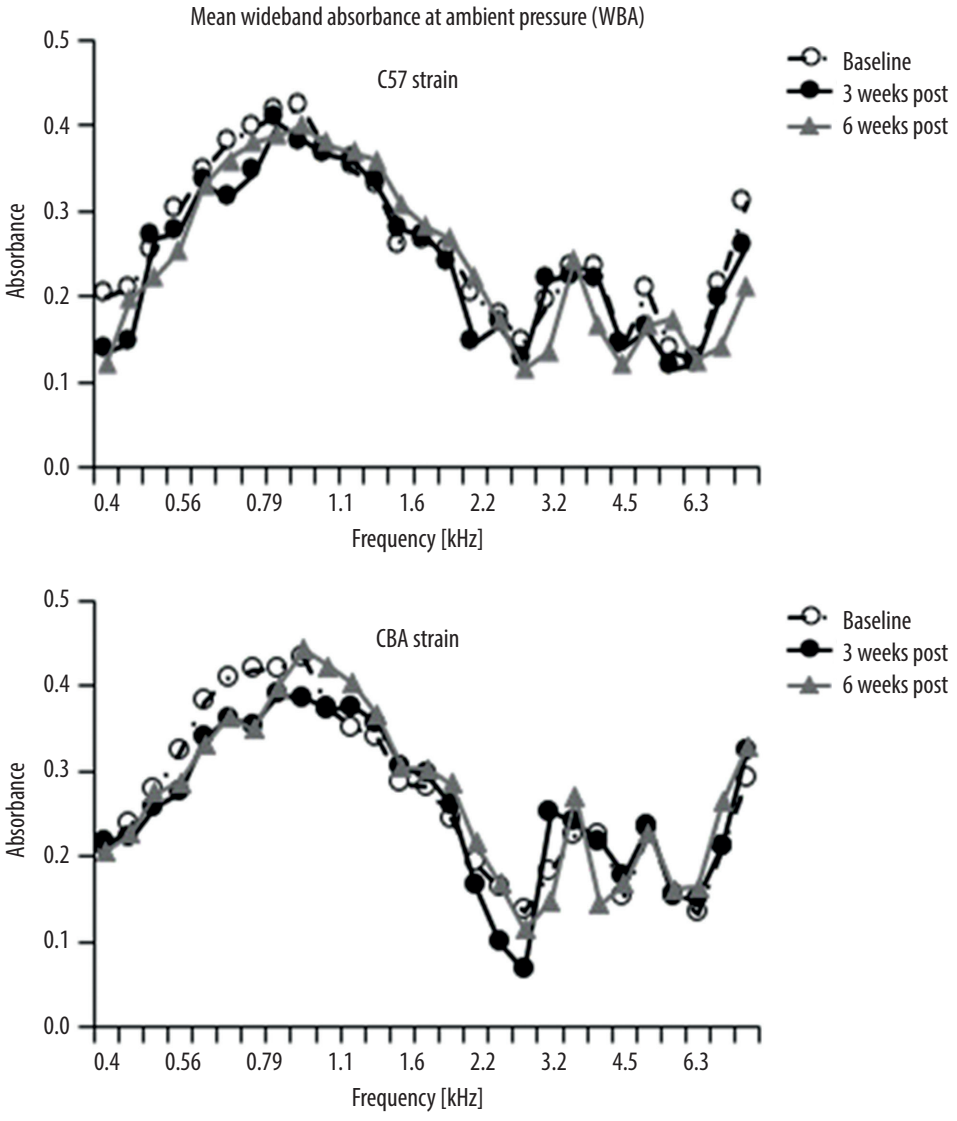

Figure 3. Mean wideband absorbance at ambient pressure versus frequency (WBA) in C57BL/6J (top, $n = 7$) and CBA/CaJ (bottom, $n = 8$) at baseline, 3 weeks post-inoculation, and 6 weeks post-inoculation with *B. hinzii*. Mean WBA in both mouse strains at 3 weeks and 6 weeks post-inoculation were unaltered and not significantly different from baseline ($p < 0.05$), suggesting that WBA lacks sensitivity in detecting histologically-verified OM

the right and left ears of each mouse strain did not show statistically significant differences between ears from 0.5 to 8 kHz for C57BL/6J strain, $t(7) = 0.812$, $p = 0.312$, nor for the CBA/CaJ strain, $t(9) = 0.914$, $p = 0.432$. Therefore, data from both ears were averaged for further analyses.

Figure 2 presents the baseline WBA versus frequency plot for each C57BL/6J infected mouse (top panel: $n = 7$, 13 ears) and CBA/CaJ mouse (bottom panel: $n = 8$, 16 ears). WBA from each mouse of the two strains exhibited similar absorbance values and patterns with the highest peak at an absorbance value of approximately 0.4 near 1 kHz, the second highest peak near 8 kHz, a slight dip at 1.6 kHz, and an M-shape between 3.2 and 6.3 kHz.

Figure 3 compares the mean WBA results from 0.5 to 8 kHz in C57BL/6J (top panel) and CBA/CaJ (bottom panel) mice at baseline, 3 weeks post-inoculation, and 6 weeks post-inoculation. The mean absorbance values and patterns follow those of the individual responses shown in **Figure 2**. Mean absorbance at 3 weeks or 6 weeks post-inoculation were not significantly different from baseline ($p < 0.05$). In both strains (C57BL/6J, top panel; CBA/CaJ, bottom panel), mean baseline WBA values were similar for the two strains at the three test times, suggesting no evidence of maturation. Repeated measures ANOVA of mean WBA were conducted for the two strains. Greenhouse–Geisser was used for sphericity correction. The C57BL/6J strain showed no statistically significant changes in mean absorbance at 3 weeks

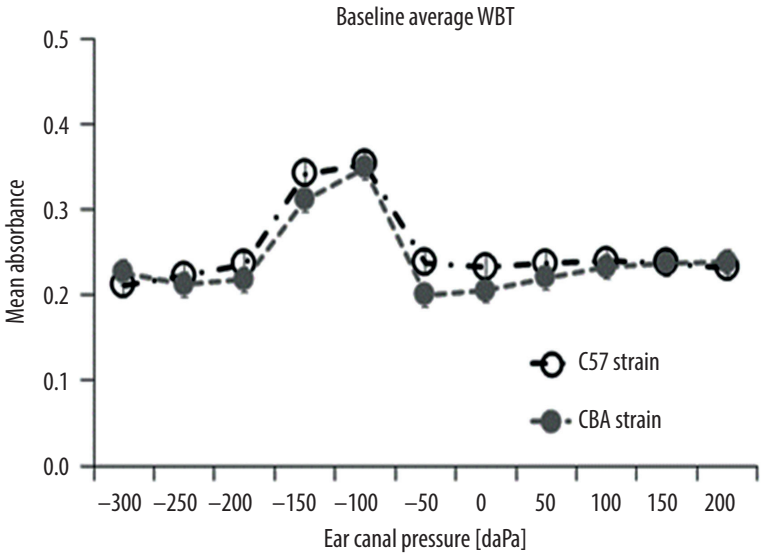

Figure 4. Mean baseline wideband tympanometry (WBT) for C57BL/6J and CBA/CaJ strains averaged across frequency for each mouse strain. WBT is averaged from 0.5 to 8 kHz and is plotted as a function of tympanometric pressure from +200 to –300 daPa. There is a single peak with highest absorbance around 0.38 at –50 daPa. Baseline WBT absorbance profiles are similar in both strains

(0.252 ± 0.034) and 6 weeks (0.251 ± 0.006) post-inoculation compared to baseline absorbance (0.265 ± 0.018) ($F = 0.696$, df = 1.257, 7.540, $p = 0.463$, $\eta_p^2 = 0.104$). The CBA/CaJ strain also showed no statistically significant changes in mean absorbance at 3 weeks (0.265 ± 0.009) and 6 weeks (0.271 ± 0.009) post-inoculation compared to baseline mean absorbance (0.273 ± 0.009) ($F = 1.740$, df = 1.914, $p = 0.213$, $\eta_p^2 = 0.199$). The lack of statistically significant changes in WBA in the C57BL/6J strain post-inoculation, despite the presence of moderate to severe OM documented histologically in the C57BL/6J group, suggests low sensitivity of WBA.

Average WBT absorbance and post-inoculations

The mean baseline WBT for C57BL/6J and CBA/CaJ strains averaged both across frequency and mice are show in **Figure 4**. The WBT is single-peaked; at baseline, the mean absorbance in both mouse strains shows a peak of approximately 4.1 around –50 daPa, with a similar absorbance profile. **Figure 5** presents the average WBT absorbance in C57BL/6J (top panel) and CBA/CaJ mice (bottom panel) averaged from 0.5 to 8 kHz and plotted as a function of tympanometric pressure (daPa) at baseline, 3 weeks post-inoculation, and 6 weeks post-inoculation with *B. hinzii*. As shown in **Figure 5**, mean WBT absorbance at 3 weeks and 6 weeks post-inoculation showed a marked reduction in peak absorbance to a nearly flat WBT profile in the C57BL/6J mice compared to baseline absorbance, suggesting the presence of OM with effusion. In contrast, the CBA/CaJ mice showed no changes in absorbance profile at 3 weeks and 6 weeks post-inoculation compared to baseline absorbance. These results indicate that C57BL/6J mice's middle ears are extremely susceptible to *B. hinzii* infection.

Table 3 presents the statistical analyses and significant post-inoculation differences of the average WBT in both strains. C57BL/6J mice showed a main effect across the three test times (baseline, 3 weeks post, and 6 weeks post *B. hinzii* inoculation) at all tympanometric pressures ($p < 0.05$). Bonferroni *post hoc* analysis revealed a significant reduction in absorbance at 3 weeks and 6 weeks post-inoculation compared to baseline absorbance ($p = 0.001$). There were no significant changes in absorbance between the 3-week and 6-week post-inoculation at –300 daPa ($p = 1.000$), –200 daPa ($p = 0.176$), –50 daPa ($p = 0.796$), and 0 daPa ($p = 0.483$), with slightly larger absorbance at 6 weeks than at 3 weeks post-inoculation at +100 daPa ($p = 0.015$) and +200 daPa ($p = 0.001$), possibly indicating an early resolution of OM. CBA/CaJ mice showed no statistically significant changes at 3 weeks and 6 weeks post-inoculation compared to baseline ($p > 0.05$). These findings suggest that C57BL/6J mice are more sensitive to *B. hinzii* infection than CBA/CaJ mice, consistent with the histological findings.

WBT absorbance in C57BL/6J mice following antibiotics

Figure 6 illustrates the temporal changes in WBT absorbance profiles in a typical C57BL/6J mouse from baseline (0 week) out to 1 week and 4 weeks post inoculation, and then during and after one month of antibiotic treatment; WBT evaluations were performed at 7, 8, and 9 weeks post-inoculation or 3, 4, and 5 weeks after the start of antibiotic treatment. At baseline (0 week), and consistent with the WBT absorbance profile of C57BL/6J mice from Experiment 1, the WBT plot shows two absorbance peaks: one at 1 kHz at –100–0 daPa and a second larger peak between 6 and 8 kHz at –300 daPa. At 1 week post-inoculation, the peak absorbance decreased at 1 kHz but increased significantly at 6–8 kHz at negative pressures compared to baseline value, followed by significant reduction of absorbance 4 weeks post-inoculation. The initial increase in absorbance at 1 week post-inoculation

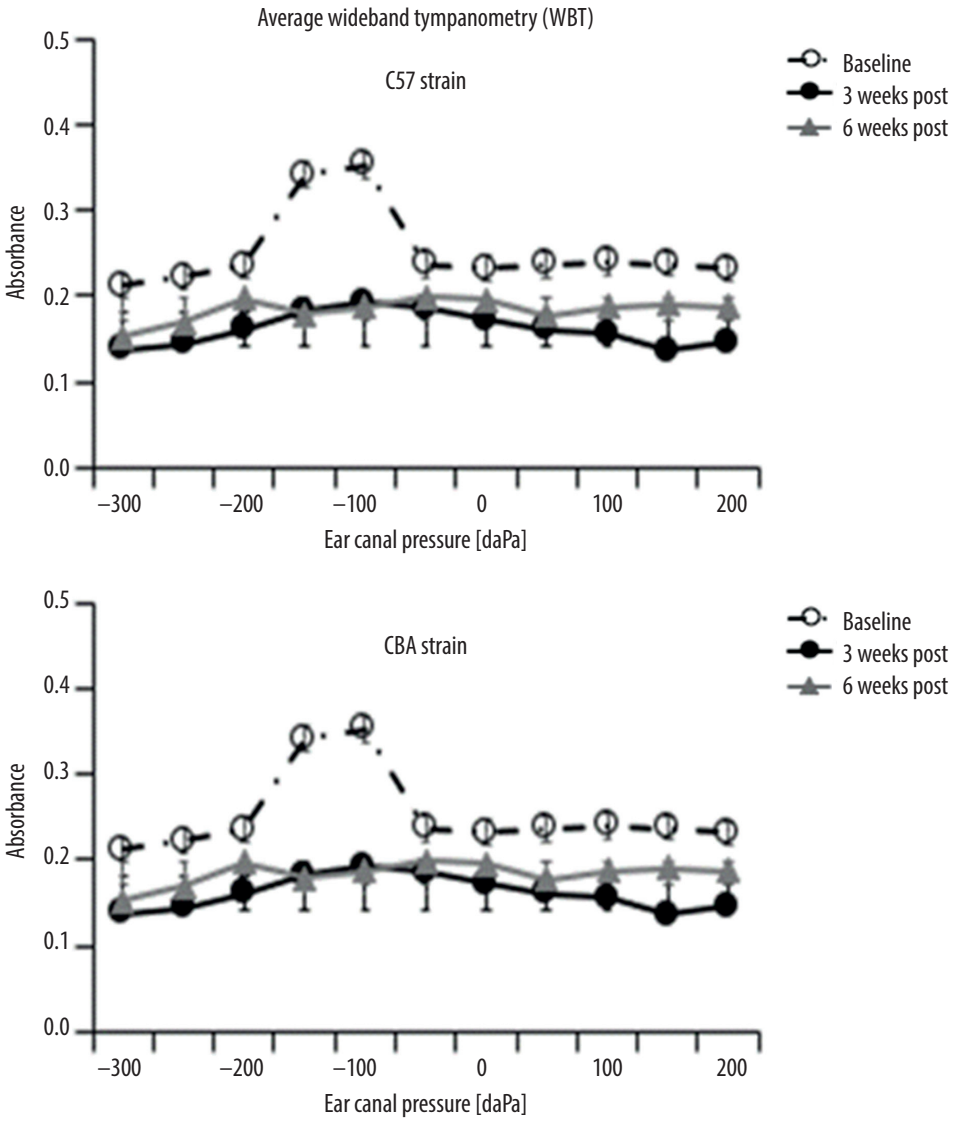

Figure 5. Mean wideband tympanogram (WBT) for two mouse strains, averaged across frequency (0.5 to 8 kHz) and plotted as a function of tympanometric pressure (+200 to –300 daPa) at baseline, 3 weeks post-inoculation, and 6 weeks post-inoculation with *B. hinzii*. The C57BL/6J strain is shown in top panel and CBA/CaJ strain at bottom. Mean WBT absorbance in C57BL/6J at 3 weeks and 6 weeks post-inoculation shows significantly reduced absorbance, resulting in a flat WBT indicative of OM. CBA/CaJ mice show no statistically significant changes in WBT absorbance at 3 weeks and 6 weeks post-inoculation compared to baseline absorbance, ruling out OM. Results indicate that C57BL/6J mice have succumbed to *B. hinzii* infection at 3 weeks post-inoculation and infection persists at 6 weeks

is consistent with negative middle ear pressure due to Eustachian tube dysfunction. This change was followed by severely reduced absorbance peaks to a nearly flat WBT profile at 4 weeks post-inoculation, indicative of the development of OM in C57BL/6J mice. After antibiotic treatment, absorbance recovered gradually over the course of antibiotic treatment and returned to baseline values at 8 and 9 weeks after antibiotic treatment. ANOVA showed a significant difference in absorbance across the four test times (baseline, 4 weeks post-inoculation, and after antibiotic treatment) ($F(2,36) = 6.231$, $p = 0.005$, $\eta_p^2 = 0.211$. Bonferroni *post hoc* analysis revealed significantly smaller absorbance at 4 weeks post inoculation compared to baseline ($p < 0.05$), and no significant difference post treatment compared to baseline ($p < 0.05$).

Histology in *B. hinzii* inoculated mice before/after antibiotics

The left panel of **Figure 7** illustrates typical histological findings in one *B. hinzii*-inoculated C57BL/6J mouse prepared for histological evaluation at a time when absorbance was reduced. The middle ear in this mouse was packed full of inflammatory material (see black arrow). The right panel of **Figure 7** illustrates the typical results in another *B. hinzii*-inoculated C57BL/6J mouse prepared for histologic evaluation 4 weeks after the start of antibiotic treatment (note: this mouse also showed a reduction of WBT at 4 weeks post-*B. hinzii* inoculation). After antibiotic treatment, the middle ear in this mouse shows a relatively clear middle ear space, with some

Table 3. One-way ANOVA comparing average WBT at different ear canal tympanometric pressure (daPa) for the C57BL/6J ($n = 13$ ears) and CBA/CaJ ($n = 16$ ears) mouse strains at three testing periods (baseline, 3 weeks post-inoculation and 6 weeks post-inoculation of *B. hinzii*

Canal pressure [daPa]	Mouse strain	*F*	*P*	η_p^2
–300	C57	5.725	0.018*	0.488
	CBA	1.217	0.328	0.158
–200	C57	17.745	<.001***	0.747
	CBA	0.032	0.968	0.005
–100	C57	37.476	<.001***	0.862
	CBA	3.437	0.066	0.923
0	C57	19.452	<.001***	0.764
	CBA	3.972	0.091	0.379
+100	C57	5.106	0.025*	0.460
	CBA	3.628	0.056	0.358
+200	C57	4.699	0.031*	0.439
	CBA	0.477	0.631	0.068

Note: Three ears from two C57BL/6J mice were excluded from the analysis due to lack of developing OM infection post-inoculation of *B. hinzii*

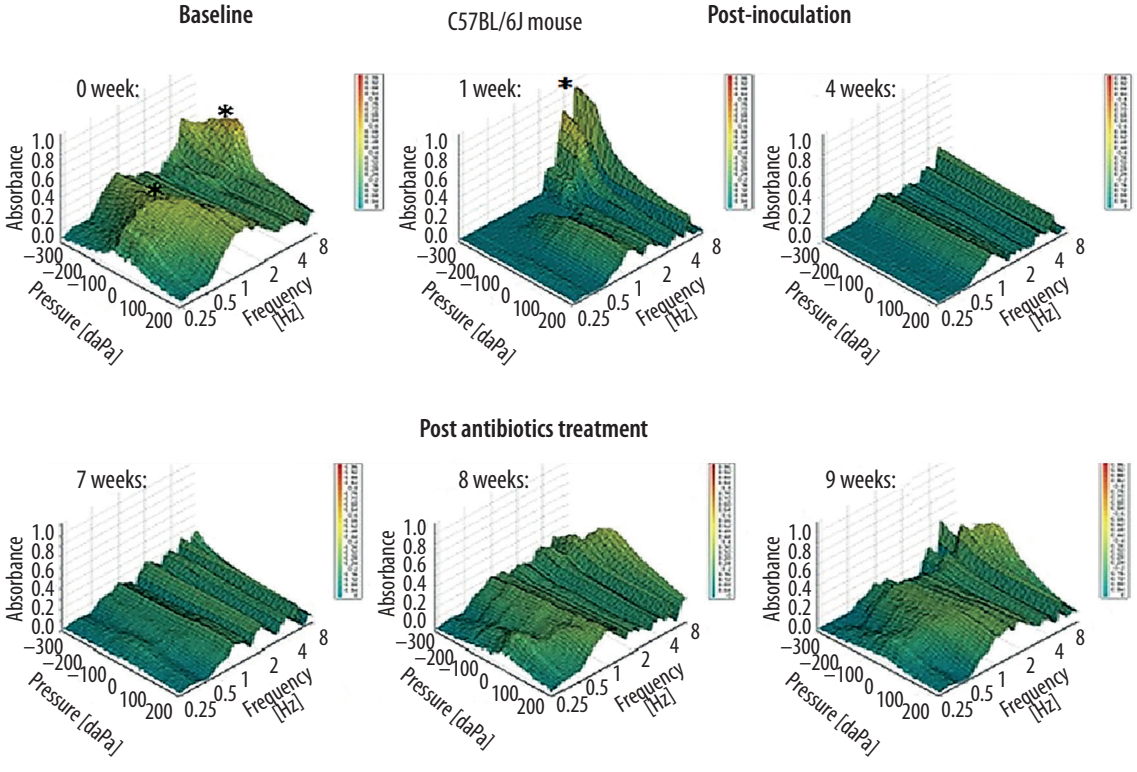

Figure 6. Changes in WBT absorbance over time from baseline (0 week), post inoculation with *B. hinzii* (1 and 4 weeks), and during continuous antibiotic treatment (7–9 weeks) in a treated C57BL/6J mouse. At baseline, two WBT absorbance peaks are present around 1 and 8 kHz (marked with *). At 1 week post-inoculation, the 8 kHz peak shows an increase in absorbance, but by 4 weeks post-inoculation, there is decreased absorbance at both regions. At 7 and 8 weeks post-antibiotic treatment, there is a gradual recovery (increase) of absorbance returning to near baseline values at 9 weeks of treatment

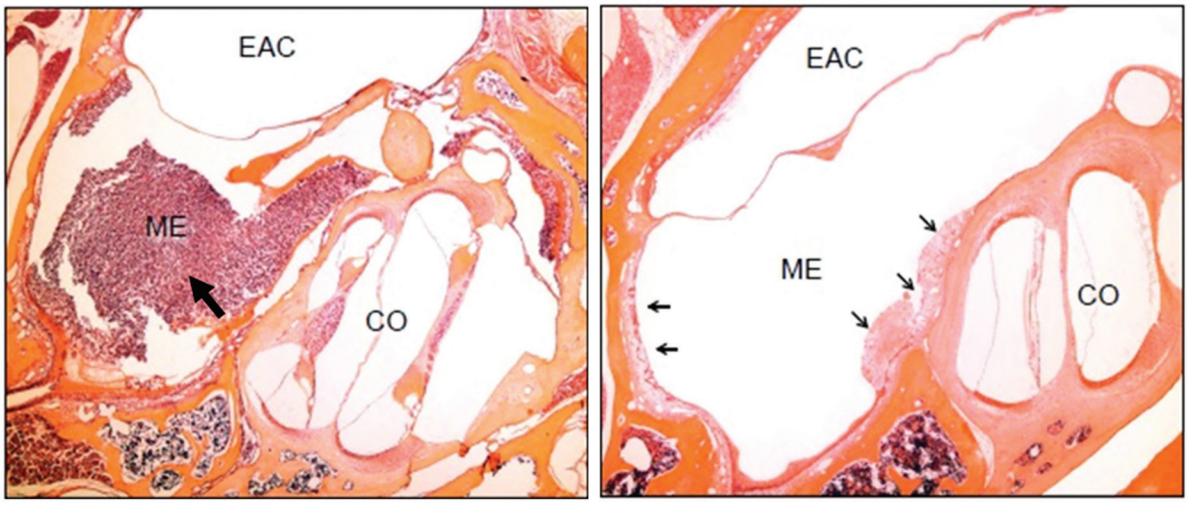

Figure 7. Histological profiles of the temporal bone region of two mice inoculated with *B. hinzii* before (left) and after (right) antibiotic treatment. Inoculation reduced wideband absorbance 4 weeks later. The mouse on the left, sacrificed and prepared for histology 4 weeks post-inoculation, shows a middle ear full of inflammatory material. The mouse on the right underwent a 4-week course of sulfamethoxazole and trimethoprim (SMTP) antibiotic treatment and was then sacrificed and prepared for histology. This mouse shows a relatively clear middle ear space, with only minor evidence of epithelial hyperplasia (arrows). Middle ear space (ME), external auditory canal (EAC), and cochlea (CO)

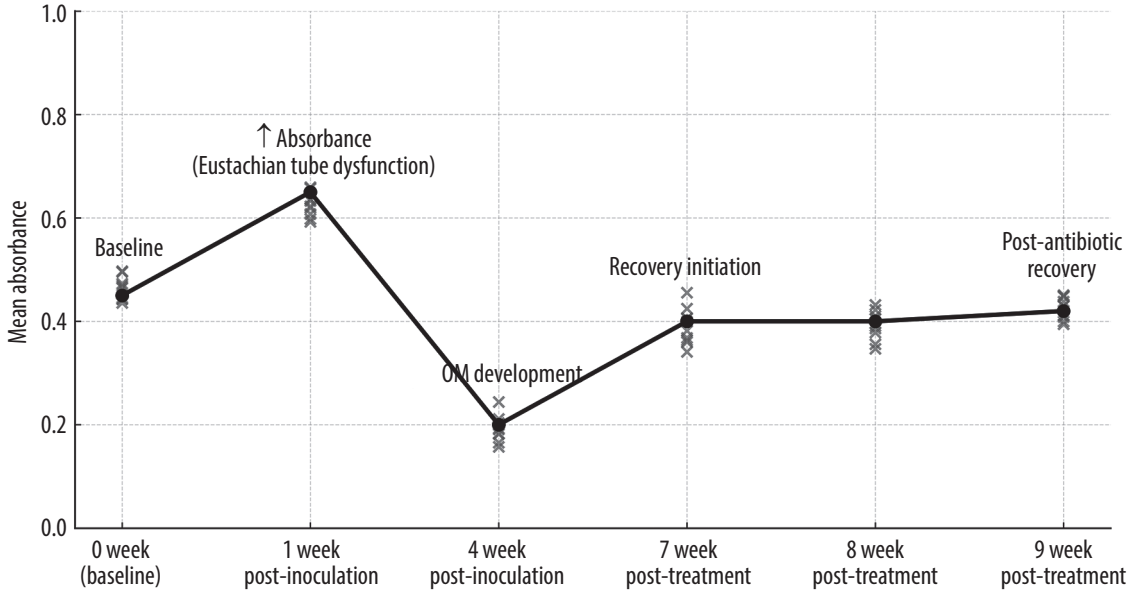

Figure 8. Time-course of wideband tympanometry (WBT) in C57BL/6J mice after inoculation with *B. hinzii*. Each gray dot represents data from an individual mouse ($n = 10$) and the black line denotes the mean absorbance at each time point. Mean absorbance increased at 1 week post-inoculation (↑ Absorbance), primarily reflecting Eustachian tube dysfunction, and decreased markedly at 4 weeks post-inoculation, consistent with the development of OM. Absorbance values progressively returned to near-baseline levels during the post-treatment period (7–9 weeks), indicating recovery and histologically confirmed resolution of OM

residual evidence of epithelial hyperplasia (black arrows). **Figure 8** illustrates the time-course of mean WBT absorbance across six measurement intervals in C57BL/6J mice. Individual data points from 10 mice are displayed to illustrate within-group variability across time. At baseline (0 week), mean absorbance was approximately 0.45. A significant increase in absorbance was observed at 1 week post-inoculation, likely reflecting altered Eustachian tube function. By 4 weeks post-inoculation, mean absorbance markedly decreased, consistent with OM development. Following antibiotic treatment, absorbance values at 7, 8, and 9 weeks post-treatment progressively improved and returned to near-baseline levels remained relatively stable, suggesting recovery and histologically confirmed resolution of OM. These findings are also consistent with the histopathological findings shown in **Figure 7**.

Discussion

Baseline WBA and WBT in young adult mice

This study is one of the first to use WAI to assess middle ear function in normal mice – before, during the development, and following the resolution of OM. WBA values provide estimates of absorbance as function of frequency at ambient pressure, whereas WBT values provide estimates of the average absorbance between 0.5 to 8 kHz at several tympanometric pressures from +200 to –300 daPa. Normal baseline measures were obtained from C57BL/6J and CBA/CaJ mice to determine if there were any significant differences in absorbance between these two widely used strains. Intra-session absorbance measured across five runs in which the probe was removed and replaced during each measurement showed good intra-session reliability, suggesting that WAI measure provides reasonably reliable estimates of absorbance across a broad range of frequencies and tympanometric pressures in mice – even though the device was not designed for species other than humans. Baseline WBA revealed two peaks, one peak near 1 kHz and a second around 8 kHz, in both C57BL/6J and CBA/CaJ mice.

Baseline WBT absorbance values, averaged from 0.5 to 8 kHz, were highest with a peak value around 0.41 in both C57BL/6J and CBA/CaJ mice when the ear canal pressure was –50 daPa. The general absorbance pattern in these two mouse strains is much different from humans. Peak absorbance in humans, which occurs near 4 kHz at 0 daPa, is approximately 0.8, a value twice that of mice [27,30]. The low absorbance values in mice likely reflects the fact that murine middle ear impedance is dominated by stiffness at frequencies below 6–8 kHz, ostensibly reducing the sensitivity of the Interacoustics device [18,36]. The Interacoustics device provides absorbance measures that cover much of the human clinical audiometric range (0.25 to 8 kHz). By contrast, the hearing range in mice ranges from approximately 1 to 80 kHz with maximum sensitivity around 20 kHz [37,38]. Given the limitations of using the Interacoustics WBT device in mice, future studies with this device might be better suited to the chinchilla, with an audiometric range similar to humans and an ear canal and middle ear space much larger than that of mice [11,39–41]. Laser doppler vibrometers are capable of measuring middle ear motion up to at least 20 kHz, making it more suitable for studies in mice with excellent high-frequency hearing [36]; however, these instruments are not readily available or suitable for most research clinicians.

Changes in WBA and WBT after inoculation of *B. hinzii*

Of the eight CBA/CaJ mice (16 ears) inoculated with *B. hinzii*, no statistically significant changes in WBA or WBT absorbance were noted at 3 weeks and 6 weeks post-inoculation compared to baseline as shown in **Figure 3** and **Figure 5**. Given that the middle ears in all CBA/CaJ mice were histologically clear of infection, the lack of change in absorbance accurately reflects the normal status of the middle ear and absence of OM in this strain following *B. hinzii* inoculation. Among the eight C57BL/6J mice inoculated with *B. hinzii*, seven developed histological evidence of OM, six had bilateral OM, and one had unilateral OM. This lack of sensitivity of WBA at ambient pressure could reflect a genuine, strain-specific biological response in which mild to moderate middle-ear changes do not substantially alter ambient absorbance across the 0.5–8 kHz band in mice. This null result could also be caused partly by using equipment mainly designed for testing human middle ears, and partly by the high stiffness of the mouse middle ear at low frequencies (stiffness dominated), making it difficult to detect absorbance changes cause by OM. Changes in absorbance might be detected in mice above 8 kHz where stiffness declines [36]. Therefore, the lack of significant WBA changes at ambient pressure should be interpreted with caution.

In contrast to our WBA results in mice, others have reported significant reductions in WBA among children with conductive hearing loss [27], Eustachian tube dysfunction [42], middle ear effusion, and tympanic membrane perforations [30]. The reductions in WBA in humans with conductive hearing loss were frequency-dependent. Decreased absorbance began around 1 kHz, increased up to approximately 4 kHz, and then rapidly decreased by 8 kHz. Thus, WBA appears to be more sensitive at detecting conductive hearing losses in humans than in mice. Possible reasons for these species difference are unclear but are likely related to species differences in ear canal and middle ear anatomy and acoustic properties, the use of the newborn calibration for the Interacoustics WBT device versus device calibration specifically optimized for mice, and possible differences in the duration and nature of the middle ear pathologies.

The average WBT revealed a significant reduction of absorbance at all tympanometric pressures at both 3 and 6 weeks post-inoculation (see **Figure 5**). The high sensitivity and specificity of WBT in detecting *B. hinzii*-induced OM in mouse is consistent with absorbance findings in patients with OM that showed 95% sensitivity and 88% specificity [43]. Notably, WBT detected OM in all mouse ears with documented OM, whereas WBT remained normal in mice with histologically normal middle ears, indicating high sensitivity and specificity. Our finding of reduced average WBT in confirmed cases of OM was noticeable at all tympanometric pressures. However, we unexpectedly observed an increase in absorbance around 6–8 kHz at negative tympanometric pressure after 1 week of infection, suggesting that C57BL/6J mice had developed negative middle ear pressure (**Figure 6**) during the early stage of infection prior to full blown OM. This finding is similar to results obtained in humans with Eustachian tube dysfunction which showed an increase in absorbance around 2–4 kHz, a result attributed to negative middle ear pressure [42]. These results suggest that WBT might be useful for detecting the negative middle ear pressure in mice associated with the early stages of OM infection.

Strain differences in OM susceptibility

C57BL/6J mice were highly susceptible to *B. hinzii*-induced OM whereas CBA/CaJ mice were highly resistant to infection for reasons that are poorly understood. Strain differences in susceptibility to various types of infections and viral-mediated cancers have been reported in the literature [44,45].

The factors that make C57BL/6J highly susceptible to *B. hinzii* are not fully understood, but some reports indicate that infected mice deficient in B cells are burdened by a greater number of bacteria [46]. Another factor that could contribute to the susceptibility of C57BL/6J mice to OM is the ability of certain bacteria to ascend the Eustachian tube into the middle ear [47]. C57BL/6J mice with compromised mucociliary transport appear to be susceptible to OM infection [48]. Other factors in C57BL/6J mice that could enhance susceptibility to pathogen-mediated infections include differences in cytokines and chemokines expression levels [49]. In addition, C57BL/6J mice have a mutation of a cadherin gene that is not only associated with early age-related hearing loss but is also known to mediate host–pathogen interactions [50]. The mutation of the cadherin 23 gene in C57BL/6J mice could allow for an opportunistic interaction with *B. hinzii* that is not present with the wild type cadherin present in CBA/CaJ mice [51]. If OM from *B. hinzii*-mediated infection is associated with this cadherin mutation, this would represent an important finding.

Recovery of WBT following antibiotic treatment

Our WBT absorbance data showed a significant reduction of absorbance 4 weeks following *B. hinzii* inoculation that recovered to baseline following the full course of antibiotic treatment. This recovery in absorbance was associated with virtually complete histological resolution of middle ear infection. These results indicate that combination antibiotic treatment (sulfamethoxazole and trimethoprim) often used to treat middle ear infections in humans was highly effective at treating OM from *B. hinzii*-mediated infection in C57BL/6J mice [34]. Because of the strong correlation with the histological findings, these results suggest that WBT measure is a reliable and highly sensitive research tool that can be used to study the development and resolution of OM and other middle ear pathologies in different murine strains infected with various pathogens. From a scientific and clinical perspective, WBT could be used to determine the susceptibility of mice with specific genetic mutations that contribute to the development of OM and other middle ear pathologies [21,44,45,50,51]. It could also be used to determine what drugs are most effective at resolving OM [52,53] or other middle ear pathologies induced by specific pathogens [4,9,54]. Our histopathological analysis following *B. hinzii* inoculation and antibiotic treatment also revealed evidence of ossicular chain remodeling in several cases, as well as minor residual infiltrates in some ears consistent with prior reports [55–57]. It is unclear if these subtle residual histopathologies would resolve with longer recovery times, longer treatments, or other antibiotics. Another related question that requires further investigation is whether the OM in the C57BL/6J mice would naturally resolve without antibiotic treatment. The outcome of such an experiment would likely depend on the sterility of the environment in which the mice were housed.

Conclusions

WAI, a recently developed technique to assess middle ear function in humans, can be used to monitor middle ear status and pathology in mice – one of the most widely used species in auditory research because of a plethora of genetic variants. The presence of *B. hinzii* bacteria in a mouse colony is a particularly serious problem for auditory researchers, because they cannot be easily eradicated by standard antibiotic administration, and because they can evade host immune responses. Our results show that WBT can be used to monitor the progression of *B. hinzii*-induced OM in mice and that a 4-week course of oral treatment with sulfamethoxazole and trimethoprim can effectively eradicate OM in C57BL/6J mice. Notably, C57BL/6J mice are highly susceptible to developing OM, in contrast to CBA/CaJ mice which are highly resistant to this form of bacterial infection.

Histological assessment of OM has confirmed the reliability and specificity of using WBT to assess the development and resolution of OM, but further research is needed to confirm the generality of these findings in other murine models, different species, and other pathologies. Although the trends in Experiment 1 and 2 were consistent and clear, a limitation of the study from a statistical standpoint was the relatively modest sample size. These statistical concerns could be overcome by increasing the numbers of mice used in Experiment 1 and 2 to enhance the statistical power of the analysis. However, the sample sizes we employed are typical of animal studies and reflect the practical concern of the large time, effort, and costs associated with performing serial measurements over an extended period. The sample sizes also reflect the ethical concern of not using an excessive number of animals for studies in which the subjects are sacrificed at the conclusion of the study. Notwithstanding statistical concerns, we believe the consistent trends observed across Experiments 1 and 2 support the general conclusions.

Another limitation of the method is that the instrument software assumes characteristic impedance values based on human ear-canal cross-sectional areas, rather than those of mice [58], so the absolute absorbance values used here need to be interpreted with caution [59]. However, this limitation is not unique to small animals; it reflects a broader, inherent constraint of WBT systems used in both human and non-human ears (IEC 60318-4, 2010). Nevertheless, although we did not calculate the mouse ear-canal equivalent volume or impedance using an in situ characteristic impedance, our findings remain valid for within-species comparisons. The use of a consistent measurement setup across all animals ensures that relative absorbance trends are meaningful and interpretable. Future studies should aim to establish the acoustically equivalent cross-sectional area of the mouse ear canal in situ in order to improve calibration accuracy and the reliability of absolute absorbance measurements. Future studies of WAI would benefit from the use of Titan instrumentation with enhanced features (e.g., having a probe with different dimensions optimized for mice and accurately measuring the ear-canal characteristic impedance and equivalent volume of mice) to test the generalizability of the current findings [30,60].

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FAMILY COHESION AND FLEXIBILITY WHEN THE CHILD HAS CENTRAL AUDITORY PROCESSING DISORDER: MOTHERS' PERCEPTIONS

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Abstract

Introduction: Families with children with auditory processing disorder (APD) can experience stress when their child encounters difficulties in communication, speech and language development, and learning. Coping with these conditions depends, among other things, on the family's cohesion and flexibility, and so it is important to understand these factors in order to provide effective psychological support. Currently, no research has explored how families with an APD child function. This study investigated family dynamics in cases where the child had APD. Based on Olson's Circumplex Model, we studied how mothers perceived the situation and examined the relationships between family cohesion and flexibility, maternal trait anxiety, and a number of socio-demographic factors.

Material and methods: There were 106 mothers of children with APD (child's average age 10 years) who participated in the study. Three groups of families were distinguished: those where the child only had APD (APD1); those with APD and speech, language, and/or articulation disorders (APD2); and those with APD accompanied by other severe health conditions (APD3). Mothers completed the Flexibility and Cohesion Evaluation Scales (FACES-IV) in its Polish adaptation (SOR) and a State–Trait Anxiety Inventory (STAI X-2).

Results: The three groups of families differed significantly in terms of the 'unbalanced' dimensions of 'disengaged' and 'rigid'. APD2 and APD3 families had higher disengaged and rigid scores compared to APD1; these scores were also higher than in the general Polish population. The mothers who had a lower education level expressed a lower level of family cohesion and had higher levels of the enmeshed and chaotic dimensions. The anxiety traits of the mothers correlated significantly with all dimensions of cohesion and flexibility, except for rigidity.

Conclusions: Families which have children with APD, especially when accompanied by difficulties in speech and language development and/or articulation or other serious health problems, may experience changes in family cohesion due to increased level of disengagement between family members. Such families, including mothers with lower levels of education and/or higher trait anxiety, would benefit from various forms of psychoeducation and psychological intervention to improve family functioning.

Keywords: children • family • trait anxiety • auditory processing disorder • APD • FACES-IV questionnaire • STAI X-2

SPÓJNOŚĆ I ELASTYCZNOŚĆ SYSTEMÓW RODZINNYCH Z DZIECKIEM Z CENTRALNYMI ZABURZENIAMI PRZETWARZANIA SŁUCHOWEGO W PERCEPCJI MATEK

Streszczenie

Wprowadzenie: Rodziny z dzieckiem z centralnymi zaburzeniami przetwarzania słuchowego (APD) mogą doświadczać sytuacji stresujących, które wiążą się z trudnościami ich dzieci w sferze komunikowania się, rozwoju mowy i języka czy uczenia się. Radzenie sobie z nimi zależy m.in. od spójności i elastyczności systemów rodzinnych, jakie tworzą. Z tego względu istotne jest poznanie ich funkcjonowania, aby następnie efektywnie udzielać psychologicznego wsparcia. Obecnie nie ma badań na ten temat. Celem badania była ocena funkcjonowania systemów rodzinnych z dzieckiem z APD w świetle Modelu Kołowego Olsona w percepcji matek, a także weryfikacja zależności między ich spójnością i elastycznością a lękiem jako cechą u matek oraz wybranymi czynnikami socjodemograficznymi.

Materiał i metody: W badaniu uczestniczyło 106 matek dzieci z APD (średnia wieku 10 lat). W celu analizy wyodrębniono trzy grupy rodzin: grupę rodzin dzieci wyłącznie z APD (APD1), grupę rodzin dzieci z APD i zaburzeniami rozwoju mowy lub/i artykulacji (APD2) oraz grupę rodzin dzieci z APD wraz innymi zaburzeniami neurorozwojowymi lub poważnymi chorobami somatycznymi (APD3). Matki wypełniły: *Flexibility and Cohesion Evaluation Scales* (FACES-IV) w polskiej adaptacji: *Skale oceny rodziny* (SOR) i *Inwentarz stanu i cechy lęku* (STAI X-2).

Wyniki: Rodziny APD1, APD2 i APD3 różnią się istotnie w wymiarach oceniających niezrównoważenie systemów rodzinnych: niezwiązania i sztywności. Podwyższone wyniki w wymiarze niezwiązania i sztywności otrzymały rodziny z grupy APD2 i APD3 względem rodzin z grupy APD1, jak i w odniesieniu do populacji ogólnej według norm polskich. Niższe wykształcenie matek dzieci z APD pozostaje w związku z mniejszym nasileniem spójności systemów rodzinnych, a z większym nasileniem w wymiarze ich splątania i chaotyczności. Lęk jako cecha korelował u badanych matek ze wszystkimi wymiarami spójności i elastyczności za wyjątkiem sztywności.

Wnioski: Rodziny z dzieckiem z APD wymagają różnych form wsparcia psychologicznego celem wzmocnienia więzi emocjonalnej i bliskości między członkami tych rodzin. Ponadto matkom dzieci z APD, zwłaszcza z niższym wykształceniem i wyższym poziomem lęku jako cechy, należałoby oferować różne formy psychoedukacji i interwencji psychologicznej umożliwiające ich systemom rodzinnym podjęcie pracy nad zwiększeniem zdolności do zmian.

Słowa kluczowe: dzieci • rodzina • lęk jako cecha • zaburzenia przetwarzania słuchowego • APD • kwestionariusz FACES-IV • STAI X-2

Key to abbreviations	
ADHD	attention deficit hyperactivity disorder
APD	auditory processing disorder
ASD	autism spectrum disorder
ASHA	American Speech-Language-Hearing Association
BAS	British Audiological Society
DD	developmental delay
DDT	dichotic digit test
DPT	duration pattern test
FACES-IV	Flexibility and Cohesion Evaluation Scales
FPT	frequency pattern test
IFPS	Institute of Physiology and Pathology of Hearing
SES	socioeconomic status
SLI	specific language impairment
SOR	Skale Oceny Rodziny [Polish adaptation of the FACES-IV]
STAI	State–Trait Anxiety Inventory
STAI X-1	State–Trait Anxiety Inventory – first part
STAI X-2	State–Trait Anxiety Inventory – second part

Introduction

Neurodevelopmental disorders or disabilities in children tend to change the way their families function. The changes affect the family's quality of life and well-being in various ways: how the roles and responsibilities within the family are shared, the quality of marital/partner relationships and social interactions, and new challenges concerning the child's rehabilitation or therapy [1–5]. In the view of Olson [6,7], a child with developmental disorders affects the functioning of the entire family, so that the effects of a child's rehabilitation/therapy and their further progress will also depend on the family's cohesion and flexibility.

The individual psychological make-up of the parents, including any psychopathology (e.g., depression, anxiety), stress, well-being, and ego-resiliency, are also important in how the family functions. Research has shown that parents in low-cohesion families score lower on these key characteristics [8–11]. On the other hand, studies have shown that families with high cohesion and flexibility assist the cognitive development of preschool children, their adjustment during the early school years [12,13], their mental health [14], and outcomes from therapy or treatment [8,15].

Olson's Circumplex Model

In a systemic approach based on von Bertalanffy's General Systems Theory, the family is treated as a whole – i.e., an open social system subject to change, pursuing goals, and self-regulating [16]. The relationships between the elements of this system, which are the family members, are determined by the roles each perform and the rules they follow, and the functioning of the family system involves communication both within it and with the external environment [17]. A change affecting one element of the family system – e.g., the health of a child – will cause changes to others (parents, siblings, grandparents), as well as to how the family functions as a whole. If we adopt a system-based approach to the mental health of children and parents, then it is the family, not the individual, that exhibits a functional disorder [18]. So in a family where a child shows varying degrees of difficulties in speech and language development, or in emotional and social development (including a neurodevelopmental disorder), then it is the family and the child who are co-responsible [1,2,8,11–15].

A salient model of system-wide family functioning is the Circumplex Model of Marital and Family Systems by Olson and colleagues [6,7,19]. In its latest published version the model uses four dimensions to describe family life: cohesion, flexibility, communication, and, less explicitly, satisfaction with family life. Cohesion is defined as the emotional bond that exists between family members [6,7] and forms a continuum from very weak (called disengagement) through moderate (balanced), to very strong (enmeshment). The next dimension, flexibility, is a measure of what changes are able to take place within the family's leadership, roles, and rules [6,7], and is assessed on a continuum ranging from rigidity, to balanced, then chaos. The third of Olson's dimensions is communication, defined as the ability to communicate positively within a family system. Finally, satisfaction with family life is implied, rather than defined, as the degree to which family members feel happy and fulfilled with each other [7,19]. Putting the four dimensions together, a healthy family is expressed in the model as having

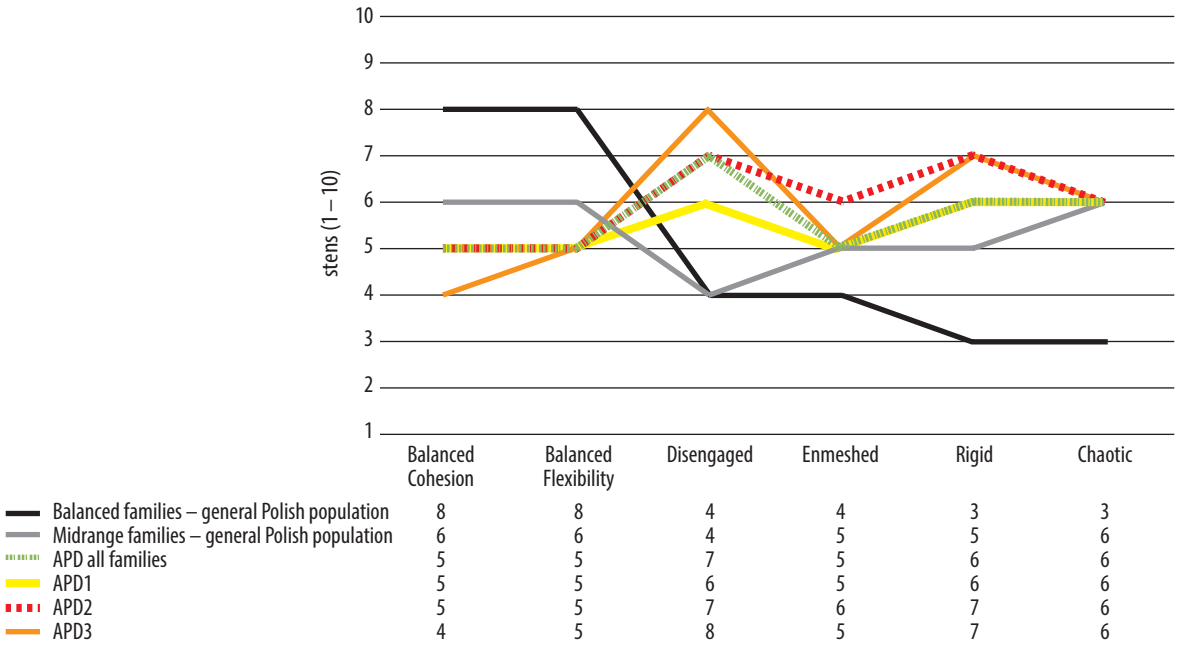

Figure 1. Profiles of families with a child with APD (FACES-IV/SOR) compared to balanced and midrange families in the Polish population

a dominance of balanced cohesion and balanced flexibility over unbalanced disengagement, enmeshment, rigidity, or chaos; it is also characterized by having effective family communication and being satisfied with family life [20].

In studies based on the Polish adaptation of the FACES-IV questionnaire, cluster analysis has been used to identify six types of families, which are somewhat different from those described by Olson [20,21]. The six types were: balanced, cohesively rigid, flexibly disengaged, midrange, rigidly disengaged, and unbalanced [21]. Balanced families were characterized by a high level of healthy functioning with high levels in the dimensions of balanced cohesion and balanced flexibility, and low levels of unbalanced disengagement, enmeshment, rigidity, and chaos (see **Figure 1**). Midrange families were those that had average scores in all balanced and unbalanced dimensions but low levels of disengagement. We regard these as generally well-functioning families, and they form the cornerstone of the present study. However, as **Figure 1** shows, the elevated level of chaos suggests these families may encounter difficulties in making joint decisions and taking action in stressful or crisis situations [21].

Research so far on families where the children have neurodevelopmental disorders or disabilities indicates that, using the theoretical Circumplex Model and the FACES-IV questionnaire, they have reduced balanced cohesion and balanced flexibility compared to healthy families. In other words, the level of unbalance generally increases, although it does seem that the level of balance or unbalance, and the deviations from the profiles typical of healthy families, can vary [11,22–25].

Studies of families where the child has been diagnosed with autism spectrum disorder (ASD) show that balanced cohesion is significantly reduced. Unbalance is increased, leading to more disengagement and more enmeshed, rigid, and chaotic behaviour [22–24]. Communication is also low, falling below Polish standards for FACES-IV, while family satisfaction remains average. As the authors of one study summarise [22], families with an ASD child appear to be at higher risk of unbalanced and rigidly disengaged behaviour than families having a neurotypically developing child.

A similar pattern is observed in families where there are preschool children with delayed speech development. For example, families of children with reduced levels of speech understanding receive lower ratings (as scored by their parents) in cohesion, communication, and satisfaction, as well as higher disengagement [11]. As another point of comparison, families with prelingually deaf children show increased levels of disengagement (as assessed by the mothers), with communication and satisfaction at average levels according to Polish norms [25].

While these studies give some insight, there have been no studies on families with an APD child that allow us to understand what difficulties such families face or what assistance they might find most helpful. What can we offer such families in terms of helping to form emotional bonds (higher cohesion), adapting to difficult family circumstances (raised flexibility), or improving family communication and family satisfaction? In brief, what is needed to make a family more cohesive and flexible? This study aims to provide some tentative answers to those questions.

APD in children

APD, sometimes called central APD or (C)APD, refers to deficits in the analysis and processing of auditory

information at the level of the central nervous system, even though peripheral hearing remains normal. According to recent data, APD occurs in 0.2–5% of the pediatric population [27], and twice as frequently in boys [28]. Children with normal intellectual abilities can have the condition [26], although APD often co-occurs with other neurodevelopmental disorders [29] – developmental dyslexia [30], attention deficit hyperactivity disorder (ADHD) [31,32], and ASD [33]. Children with APD often experience difficulties in the motor and emotional-social spheres [34–36].

The British Audiological Society (BAS) broadly characterizes APD as displaying abnormal discrimination, separation, grouping, localization, and organization of sound stimuli [37]. Difficulties associated with APD may manifest in terms of speech comprehension, especially in unfavorable acoustic conditions (for example, noise). Higher auditory functions are performed incorrectly, giving rise to difficulties in locating sound, distinguishing and recognizing sound patterns, and understanding distorted speech or speech accompanied by competing signals [38]. APD may contribute to speech and language development disorders and learning difficulties [37].

A feature of children with APD is that they react variably to auditory stimuli. Thus, they sometimes seem not to understand commands, and their response to a verbal command may be slow, as if they need more time to assimilate the information they hear. In addition, they may have difficulty remembering verbal information, especially understanding long or complex instructions, and will often ask for them to be repeated. They may also have difficulty discriminating volumes and different sound locations, and are easily distracted. Children with APD typically have difficulty concentrating and become fatigued during prolonged or complex auditory activities. Often there are reading, articulation, and language difficulties [39]. Some 47% of children aged 7–12 with APD have language development disorders and reading difficulties [40].

From the parents' point of view, APD has negative psychosocial consequences, and children diagnosed with this disorder often experience difficulties at school [34,35]. According to qualitative research conducted in New Zealand, children with APD can show increased levels of anxiety, anger, tantrums, and frustration due to difficulties in communicating with both teachers and peers. Children with APD may experience a lack of understanding from their peers, isolation in the social life of the school, and at the same time show a tendency to socialize with children with various disorders, such as ASD or apraxia [35]. In the cited studies, parents of children with APD report dissatisfaction with educational support, while parents in Poland have rated the quality of their family life low, with a lack of specialist support for families with APD children, support from other people, and level of social interaction [5].

Aim of the study

The aim of the study was to assess, based on mothers' perceptions, the cohesion and flexibility of families with children with APD – based on families where the child had been diagnosed with APD only, families where the child with APD had difficulties in speech and language development and/or articulation, and families where the child had not only APD but other disorders/somatic diseases such as ASD, ADHD, asthma, and diabetes. For added perspective, the study looked at the level of trait anxiety in the mothers and how it related to the dimensions of family functioning as assessed by the Olson Circumplex Model [6,7].

Material and methods

Participants and procedure

The study invited the participation of mothers of children diagnosed with APD and was conducted between September 2024 and March 2025 while the children were undergoing auditory training organized by the Institute of Physiology and Pathology of Hearing. The research had a cross-sectional design and was anonymous and voluntary. Mothers were given pencil-and-paper questionnaires to complete during auditory training, which they placed in a designated box in the rehabilitation center. The response rate was approximately 60%. All participants lived in central Poland. The inclusion criteria for mothers and their children with APD were as follows: Polish nationality, children aged 6 to 17, diagnosis of APD in the child, and willingness of the child and its mother to participate in auditory training.

The mothers were aged between 28 and 55 ($M = 41.7$, $SD = 4.9$). Their children were diagnosed with APD according to the criteria published by the American Speech-Language-Hearing Association (ASHA) [38]. The children were aged between 82 and 204 months ($M = 124.3$, $SD = 30.3$). In all children the diagnosis of APD was made by a qualified audiologist who was a medical doctor and was based on a comprehensive assessment that included psychoacoustic tests: the dichotic digit test (DDT), the frequency pattern test (FPT), and the duration pattern test (DPT) [41].

During a consultation with three other specialists (a speech therapist, psychologist, and pedagogue), the mothers obtained information about their child's speech and language development and received reports about other health problems identified in their child, including ADHD, ASD, developmental delay (DD), specific language impairment (SLI), and dyslexia; they also received documents from relevant medical or educational institutions. The children and their mothers were divided into three groups for the study: APD1 – families with children with APD only and no other health problems; APD2 – families with children with APD plus speech/language development and/or articulation disorders (excluding SLI); and APD3 – families with children with APD plus serious health problems (e.g., ADHD, ASD, diabetes, asthma).

Tables 1 and 2 presents the sociodemographic data of the mothers and children according to APD1, APD2, and APD3. Statistically significant intergroup differences were found in the gender distribution of the children ($\chi^2 = 9.19$, $p = 0.01$), with the highest percentage of boys (91%) in the APD3 group.

Table 1. Maternal sociodemographic characteristics for children with APD; intergroup comparisons between APD1, APD2, and APD3

Mothers *n* = 106	APD1 *n* = 40	APD2 *n* = 44	APD3 *n* = 22	Significance of intergroup comparison
APD type – *n* (%)	40 (37.7%)	44 (41.6%)	22 (20.7%)	
Age (years) – M (SD)	43.0 (4.1)	41.04 (5.6)	40.9 (4.3)	$F = 2.089$; $p = 0.129$
Max	55	52	52	
Min	35	26	33	
Education				
Below master's degree – *n* (%)	11 (27.5%)	23 (52.3%)	8 (36.4%)	$\chi^2 = 5.49$; $p = 0.06$
Completed master's degree – *n* (%)	29 (72.5%)	21 (47.7%)	14 (63.6%)	
Marital/partnership status				
In a relationship – *n* (%)	34 (85%)	39 (89%)	21 (96%)	$\chi^2 = 1.54$; $p = 0.462$
Single – *n* (%)	6 (15%)	5 (11.4%)	1 (4.5%)	
Number of children – M (SD)	2.17 (0.93)	2.13 (0.76)	1.95 (0.78)	$H(2.106) = 0.72$; $p = 0.69$*
Max	6	4	3	
Min	1	1	1	

* Kruskal–Wallis rank test

Table 2. Sociodemographic characteristics of children with APD; intergroup comparison between APD1, APD2, and APD3

Children with APD *n* = 106	APD1	APD2	APD3	Significance of intergroup comparison
Sex				
Girls *n* (%)	18 (45%)	19 (43.18%)	2 (9.1%)	**$\chi^2 = 9.19$; $p = 0.01$**
Boys *n* (%)	22 (55%)	25 (56.82%)	20 (90.9%)	
Age M (SD)	128.87 (35.5)	119 (25.85)	126.86 (28.36)	$F = 1.2$; $p = 0.304$
Max	204	200	196	
Min	84	82	85	
Children/adolescents (months)				
Children (0–131 mo) *n* (%)	22 (55%)	34 (77%)	13 (59%)	$\chi^2 = 5.01$; $p = 0.08$
Adolescents (132–215 mo) *n* (%)	18 (45%)	10 (23%)	9 (41%)	
Siblings				
None – *n* (%)	7 (18%)	8 (18%)	7 (32%)	$\chi^2 = 3.38$; $p = 0.49$
One – *n* (%)	25 (63%)	24 (55%)	9 (41%)	
Two or more – *n* (%)	8 (20%)	12 (27%)	6 (27%)	

The Bioethics Committee of the Institute of Physiology and Pathology of Hearing approved the study (IFPS/6/2024).

Measures

To assess the functioning of families with children with APD, we used the questionnaire Skale Oceny Rodziny (SOR) [21,42], which is a Polish adaptation of FACES-IV by Olson et al. [20]. SOR consists of 62 items that form 8 scales. Two of them assess balanced conditions: Balanced Cohesion and Balanced Flexibility, and 4 assess unbalanced conditions, namely Disengagement, Enmeshment, Rigidity, and Chaos. In addition, FACES-IV/SOR includes two more scales: Family Communication and Family Life Satisfaction. The first 6 scales (each containing 7 items) allow for ratings from 1 to 5, so that a score for each scale can be obtained in the range 7 to 35 points. The scales of Family Communication and Satisfaction are scored from

10 to 50 points. SOR also carries standard sten scores to compare results with the general Polish population [42].

The level of trait anxiety was assessed using the Polish adaptation of the State–Trait Anxiety Inventory (STAI) [43] developed by Spielberger et al. [44]. The STAI questionnaire consists of two parts, each containing 20 statements. The first part of the STAI (X-1) is used to assess the level of 'state anxiety' treated as a present emotional state, while the second part (X-2), which was used in this study, concerns 'trait anxiety' understood as an inherent personality trait. Trait anxiety is an individual's disposition to perceive objectively harmless situations as threatening, and so responding to them with an unrealistically high level of anxiety. Responses are scored on a scale of 1 to 4, so the total score ranges from 20 to 80 points. A higher total score represents a higher level of trait anxiety. Again, the Polish adaptation of the STAI has sten standards for the Polish population [43].

The raw scores (*M*) were compared with Polish sten standards published in manuals for FACES-IV/SOR [41] or STAI-trait [42]. In this way they were assigned levels of low (1–3 sten), low average (4 sten), average (5–6 sten), high average (7 sten), and high (8–10 sten).

Statistical analysis

Statistical analyses were performed using SPSS v. 29. Descriptive statistics were calculated to assess data distribution and central tendencies. The Shapiro–Wilk test was used to verify the normality of the distributions. Pearson's chi-square (χ^2) tests and ANOVA/Kruskal–Wallis rank tests were used to assess differences between the APD1, APD2, and APD3 groups in terms of sociodemographic characteristics (**Tables 1 and 2**).

Differences in FACES-IV/SOR between the three groups of mothers (APD1, APD2, APD3) were assessed using ANOVA or Kruskal–Wallis rank tests, and in STAI (X-2) using ANOVA (**Table 3**). A *t*-test or Mann–Whitney *U*-test was used to compare the results of mothers of children with APD in the FACES-IV and STAI (X-2) questionnaires according to their level of education (low, education below master's degree; high, completed master's degree). We also wanted to examine correlations between the family functioning dimensions of FACES-IV/SOR and the mothers' anxiety traits (STAI-trait). Here, Pearson's correlation coefficients or Spearman's *rho* coefficients were calculated for all participants and for the APD1, APD2, and APD3 groups. Statistical significance was set at $p < 0.05$.

Results

Table 3 presents intergroup comparisons (ANOVA or Kruskal–Wallis test) for groups of mothers of children with APD1, APD2, and APD3 for the FACES-IV/SOR and STAI-trait questionnaires. The columns show the scores (*M*, *SD*) for the entire group of mothers of children with APD, as well as for the three groups separately (APD1, APD2, APD3); they also list the results of the statistical tests used, along with the level of statistical significance.

For the present study we calculated Cronbach's alpha reliability coefficients for SOR, and the findings were as follows: Balanced Cohesion 0.78, Balanced Flexibility 0.76, Disengagement 0.82, Enmeshment 0.55, Rigidity 0.60, Chaos 0.73, Family Communication 0.92, and Family Satisfaction 0.91.

For the purpose of creating a profile of all families with children with APD (APD all), as well as separate groups of families (APD1, APD2, and APD3), results from the FACES-IV questionnaire scales were converted to sten standards; they included Balanced Cohesion, Balanced Flexibility, Disengagement, Enmeshment, Rigidity, and Chaos, as shown in **Figure 1**. The figure also shows two types of family profiles (Balanced families and Midrange families) obtained from studies of the general Polish population [21,42].

Intergroup comparisons were statistically significant only for two scales of FACES-IV/SOR: Disengaged and Rigid (**Table 3**). Post hoc tests (**Table 4**) between the three groups of families of APD children (APD1, APD2, APD3) showed that, on the Disengaged and Rigid scales, the results for APD1 families were significantly lower than for APD2 and APD3 families; furthermore, the latter two groups of families did not differ significantly from each other.

The levels of anxiety trait (STAI-trait) were similar among the groups of mothers and were average according to Polish norms. All the families were elevated on the Disengaged scale (a high average).

Correlation analysis revealed that the correlations (Pearson's *r* or Spearman's *rho*) between FACES-IV/SOR and STAI-trait questionnaires were statistically significant and, in the majority of them, of moderate magnitude both in the full group of families of children with APD and in the subgroups APD1, APD2, and APD3 (**Table 5**). Of some concern, there were significant relationships ($p < 0.05$ to $p < 0.001$) between most dimensions of FACES-IV/SOR and the level of anxiety trait in mothers. The notable exception was the Rigid dimension, where $p > 0.05$.

Among the sociodemographic variables, only the education level of the mothers appeared to play a significant role in the functioning of their families (**Table 6**). A comparison (*t*-test, Mann–Whitney *U*-test) of mothers with lower levels of education (below master's degree in this study) with mothers with higher levels of education (beyond a master's degree) revealed significant differences on three scales: Balanced Cohesion, Enmeshed, and Chaotic (**Table 6**). The results indicate that mothers with a lower level of education perceived their families as having lower Balanced Cohesion, but higher levels of Enmeshed and Chaotic.

Discussion

The present research has revealed how, as perceived by mothers, families with a child with APD function. The research used a system-based approach following Olson's Circumplex Model. Comparisons were made between three groups: families of children with APD but no accompanying difficulties (APD1 group), children with APD and difficulties related to speech and language development

Table 3. Intergroup comparisons (ANOVA, Kruskal–Wallis rank test) of mothers of children with APD1, APD2, and APD3 based on scores on FACES-IV/SOR and STAI-traits. Scores are also compared to Polish sten standards (1–10) [41]

Measures	APD *n* = 106 *M* (*SD*) stens 1–10	APD1 *n* = 40 *M* (*SD*) stens 1–10	APD2 *n* = 44 *M* (*SD*) stens 1–10	APD3 *n* = 22 *M* (*SD*) stens 1–10	ANOVA, *F*(*p*); Kruskal–Wallis rank test, *H*(*p*)
FACES-IV/SOR Balanced Cohesion (range 7–35)	28.51 (5.12) 5 sten (average)	29 (5.45) 5 sten (average)	28.4 (4.26) 5 sten (average)	27.86 (6.18) 4 sten (low av.)	*H* = 1.07; *p* = 0.586
FACES-IV/SOR Balanced Flexibility (range 7–35)	24.82 (5.33) 5 sten (average)	24.57 (5.63) 5 sten (average)	24.79 (5.10) 5 sten (average)	25.31 (5.47) 5 sten (average)	*H* = 0.629; *p* = 0.73
FACES-IV/SOR Disengaged (range 7–35)	13.54 (5.68) 7 sten (high av.)	11.82 (5.04) 6 sten (average)	14.31 (6.15) 7 sten (high av.)	15.13 (5.21) 8 sten (high)	*H* = 7.661; ***p* = 0.022**
FACES-IV/SOR Enmeshed (range 7–35)	13.66 (4.29) 5 sten (average)	12.82 (3.78) 5 sten (average)	14.47 (4.77) 6 sten (average)	13.54 (4.00) 5 sten (average)	*H* = 2.562; *p* = 0.278
FACES-IV/SOR Rigid (range 7–35)	18.3 (4.70) 6 sten (average)	16.6 (4.61) 6 sten (average)	19.04 (4.18) 7 sten (high av.)	19.9 (5.07) 7 sten (high av.)	*H* = 6.866; ***p* = 0.032**
FACES-IV/SOR Chaotic (range 7–35)	16 (5.53) 6 sten (average)	15.55 (5.17) 6 sten (average)	16.61 (5.78) 6 sten (average)	15.59 (5.81) 6 sten (average)	*F* = 0.457; *p* = 0.634
FACES-IV/SOR Family Communication (range 10–50)	38.09 (8.44) 5 sten (average)	39.4 (7.19) 5 sten (average)	37.31 (9.53) 5 sten (average)	37.27 (8.28) 5 sten (average)	*H* = 1.033; *p* = 0.596
FACES-IV/SOR Family Satisfaction (range 10–50)	37.26 (8.02) 6 sten (average)	38.45 (7.64) 7 sten (high av.)	36.86 (7.85) 6 sten (average)	35.90 (9.07) 5 sten (average)	*F* = 0.802; *p* = 0.451
STAI (X-2)-trait total (range 20–80)	(*n* = 101) 42.68 (9.61) 5 sten (average)	(*n* = 39) 43.94 (9.63) 6 sten (average)	(*n* = 42) 41.95 (8.89) 5 sten (average)	(*n* = 20) 41.75 (11.16) 5 sten (average)	*F* = 0.548; *p* = 0.58

Table 4. Post hoc comparison between APD1, APD2, and APD3 families based on the Disengaged and Rigid scales of FACES-IV/SOR

	Comparison	*p*
FACES-IV/SOR Disengaged	APD1 – APD2	**0.043**
	APD1 – APD3	**0.010**
	APD2 – APD3	0.352
FACES-IV/SOR Rigid	APD1 – APD2	**0.034**
	APD1 – APD3	**0.021**
	APD2 – APD3	0.574

and/or articulation (APD2 group), and children who had other serious health problems (APD3 group). The relationships between family functioning and anxiety trait in mothers, as well as sociodemographic factors, were also examined, and of the latter only the mothers' educational level was found to be significant.

We found (**Figure 1**) that the profile of all families with children with APD, created on the basis of the FACES-IV/SOR questionnaire, differed from the profile obtained for families regarded as healthy (i.e., balanced and midrange family types, according to Polish standards [21,42]). The levels of Balanced Cohesion and Balanced Flexibility (5 sten) were lower, although still average according to Polish standards. The levels of unbalanced dimensions, primarily Disengagement (7 sten) and Rigidity (6 sten), were higher than in balanced and midrange families, as illustrated in the figure.

Based on the functioning assessments of all families with children with APD (FACES-IV/SOR) (**Figure 1**), it can be said that there is a risk of reduced family cohesion in these families. This is indicated in the figure by the average level of Balanced Cohesion (which is lower than in balanced and midrange families), as well as the increased level of Disengagement. This is especially the case in families

Table 5. FACES-IV/SOR and STAI-trait questionnaire correlations (*r* Pearson, *rho* Spearman) for the whole group of mothers of children with APD and of the groups separately (APD1, APD2, APD3)

Groups of families with children with APD	All APD *n* = 101	APD1 *n* = 39	APD2 *n* = 42	APD3 *n* = 20
Variables	**STAI (X-2)-trait total**			
FACES IV/SOR Balanced Cohesion	*rho* = –0.47***	*rho* = –0.44**	*r* = –0.51***	*rho* = –0.56**
FACES IV/SOR Balanced Flexibility	*rho* = –0.46***	*r* = –0.45**	*r* = –0.40**	*rho* = –0.50*
FACES IV/SOR Disengaged	*rho* = 0.44***	*rho* = 0.34*	*r* = 0.60***	*r* = 0.56**
FACES IV/SOR Enmeshed	*rho* = 0.31**	*rho* = 0.38*	*r* = 0.46**	*rho* = 0.01 ns
FACES IV/SOR Rigid	*rho* = –0.02 ns	*r* = –0.31 ns	*r* = 0.02 ns	*rho* = –0.11 ns
FACES IV/SOR Chaotic	*r* = 0.48***	*r* = 0.45**	*r* = 0.48**	*r* = 0.61**
FACES IV/SOR Family Communication	*rho* = –0.54***	*rho* = –0.37*	*rho* = –0.72***	*rho* = –0.60**
FACES IV/SOR Family Satisfaction	*rho* = –0.62***	*r* = –0.43**	*r* = –0.70***	*r* = –0.69***

Note: ns – not significant; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$

Table 6. Intergroup comparisons (*t*-test, Mann-Whitney *U*-test) of mothers' education level – below master's degree (low) or completed master's degree (high) – based on scores of FACES-IV/SOR

FACES-IV/SOR	Mothers' education		Statistical test
	Low (below master's degree) *n* = 42, *M* (*SD*)	High (completed master's degree) *n* = 64, *M* (*SD*)	
Balanced Cohesion (range 7–35)	27.23 (5.44)	29.35 (4.77)	*U* = 1700.5 ***p* = 0.021**
Balanced Flexibility (range 7–35)	23.90 (5.85)	25.42 (4.92)	*t* = –1.43 *p* = 0.153
Disengaged (range 7–35)	14.73 (5.94)	12.76 (5.41)	*U* = 1063.5 *p* = 0.069
Enmeshed (range 7–35)	14.88 (4.58)	12.85 (3.92)	*U* = 995.5 ***p* = 0.024**
Rigid (range 7–35)	18.90 (4.41)	17.90 (4.87)	*t* = 1.07 *p* = 0.287
Chaotic (range 7–35)	17.95 (5.35)	14.71 (5.310	*U* = 878 ***p* = 0.003**
Family Communication (range 10–50)	36.45 (9.45)	39.17 (7.58)	*U* = 1562.5 *p* = 0.158
Family Satisfaction (range 10–50)	36.28 (7.77)	37.90 (8.18)	*U* = 1540.5 *p* = 0.204

in the APD3 and APD2 groups. Families characterized by a higher disengagement rate may have rigid boundaries, which manifest themselves in indifference, low support, and emotionally distant relationships between family members. They are also characterized by low levels of positive affect, as well as diminished engagement and parental intrusiveness [12]. As shown by Sturge-Apple et al. (2010) [12], a family characterized as disengaged is likely to have a child who adjusts poorly to school during the early years.

The profile of APD3 families shown in **Figure 1** is noteworthy. Such families have reduced Balanced Cohesion (orange line), which is the same level (4 sten) as seen in cases of families with autistic children [23,24] or children with speech delay [11]. At the same time, the level of disengagement (8 stens) and rigidity (7 stens) is high relative to the norms for the general population (black and grey lines). Based on these results, as well as the other findings from the FACES-IV questionnaire, we hypothesize that

APD3 families tend towards a rigidly-disengaged family profile, and this points to a level of difficulty in these families. A similar conclusion can be drawn with regard to APD2 families (red dotted line), as they do not differ significantly in terms of disengagement and rigidity. The rigidly-disengaged family was identified in studies by Margasiński on the Polish general population [21,42] and also by Everri et al. [45] on Italian adolescents. Both studies found that in difficult situations, family members tended to become rigid in their attitudes, exercise excessive control, and impose strict rules – all at the expense of family cohesion. The rigidly-disengaged family is characterized by a lack of emotional closeness and support, leading to feelings of loneliness and misunderstanding within the family, as well as to difficulties in communicating feelings and needs [21,42].

Following Olson's model [6], family communication is linked to the formation of family bonds. Improved functioning in this area can be a starting point for changes in cohesion and flexibility, including of course in families of children with APD who are at risk of disengagement and rigidity in relationships and decision-making. It is worth noting that, regardless of the group of families of children with APD, the mothers thought that family communication remained at a similar average level (**Table 6**). This is a somewhat surprising result and requires further research. We still do not know how family communication is assessed among the balanced and midrange families of the Polish population [21,42]. Nevertheless, the level of family communication we observed was higher than that in families of children with delayed speech development [11] or with ASD [23,24].

In other dimensions of Olson's Circumplex Model – cohesion, flexibility, and communication – satisfaction with family life depends on how the family functions [21,42]. This also includes families where the child has a disorder, disability, or illness, as demonstrated, for example, in families with a deaf child [25]. In our study of APD families, satisfaction with family life also proved to be average relative to the norms for the general Polish population. Nevertheless, as noted above, there is still no data on the satisfaction of balanced or midrange families in Poland, a situation that also applies to the dimension of family communication [21,42]. The highest level we saw (high average) was from families in the APD1 group. Note also that these families also scored a high average in the other dimensions of family functioning.

Despite the high average scores, the level of family satisfaction as assessed by mothers of children with APD was generally lower (7 stens) than that obtained in other studies of Polish adults, mostly women, concerning family functioning, life satisfaction, and emotional intelligence [46]. This general consistency indicates that APD families are usually less satisfied with family life, a result also found in families where the child has ASD [47] or hearing loss [25].

We found that mothers of children with APD exhibited an average level of trait anxiety compared to the general Polish population [44], irrespective of APD1, APD2, or APD3. However, the level is higher than in parents of typically developing children found in other Polish studies on parents of children with nephrotic syndrome [48]. This result is also supported by the reduced level of emotional stability in mothers of children with APD [49] in which the Big Five personality trait of emotional stability negatively correlated with anxiety [50]. We suggest that psychological interventions aimed at reducing anxiety should be offered to mothers of children with APD who report elevated levels of anxiety.

As the results indicate, lower anxiety traits co-occur with higher levels of Balanced Cohesion and Flexibility in families. On the other hand, the higher the intensity of trait anxiety, the higher were the levels of the three dimensions of family unbalance – disengagement, enmeshment, and chaos – with the exception of the dimension of rigidity of the family system (**Table 6**). The rigidity deserves comment. The rigidity dimension of all APD families was average, but it was higher than in the balanced and midrange families [21,42], as shown in **Figure 1**. No significant correlation was found between rigidity and the severity of anxiety in mothers of children with APD. Similarly to other studies, there was no association between rigidity and other psychological dimensions such as life satisfaction [25,46] or emotional intelligence [46], suggesting that family system rigidity is independent of individual psychological characteristics. The validity of the Rigidity scale in the FACES-IV/SOR questionnaire may be questioned too, implying that Rigidity may be measuring a construct other than the targeted one (that is, is the rigidity of the family system as perceived by family members).

Among the sociodemographic factors, the education level of the mothers of children with APD was found to play a significant role in terms of balanced cohesion, enmeshment, and chaos. Mothers with lower education levels belonged to families which functioned, in the mothers' view, with lower cohesion; these families also functioned with more enmeshment and chaos. A relationship between lower family cohesion and socioeconomic status (SES), a component of which is the parent's level of education, can be identified indirectly, in that we found that lower SES was associated with higher stress, lower parental availability, and limited access to developmental resources. Together these factors are expected to co-occur with lower cohesion, communication, and adaptability [51,52].

It remains something of a paradox, however, that other Polish studies on the functioning of family systems have not found such a relationship, even though they all followed Olson's Circumplex Model [11,23,25]. This implies that further research is required here. In resolving the paradox, the criterion we used to categorize mothers as having lower or higher education probably needs more scrutiny. In studies where no correlation between level of education and cohesion or flexibility was found, higher education was defined as having completed a bachelor's degree. We do not know whether the difference between a bachelor's and a master's degree is significant in terms of APD. Other limitations of our study include the manner in which families of children with APD were recruited – mothers were selected exclusively from those who participated in our Institute's rehabilitation programs of auditory training for APD children. These mothers may have been especially proactive and caring in taking action on

behalf of their children. The families studied lived in central Poland and therefore might have had better access to services for children with APD. Another limitation is that the source of information about comorbid conditions in children with APD was the mothers themselves, rather than the child's medical records.

Of course, a larger sample size would be better for identifying the types of families of children with APD according to Olson's Circumplex Model and for relating the findings to the broader Polish population [21,42]. As well as examining the validity of the Rigid scale from the FACES-IV-SOR questionnaire, the question of what level of satisfaction with family life characterizes balanced and mid-range families (considered to be "healthy families") needs to be addressed.

Conclusions

The results of the study show that APD in children, especially when accompanied by difficulties in speech and language development and/or articulation or other serious health problems, can modify the way their families function. In terms of Olson's Circumplex Model, the impact primarily affects cohesion, so that there is an increase in disengagement. If there is a problem, it is advisable that the affected family receives some form of psychological diagnosis [53].

Mothers of children with APD who have lower levels of educational attainment, or show elevated levels of trait anxiety, also need psychological assistance. This would hopefully improve the functioning of the entire family system. For a start, psychological interventions need to focus on effective communication between family members, and thus on maintaining and strengthening emotional bonds and a sense of closeness.

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LOW-FREQUENCY COCHLEAR IMPLANT (CI) STIMULATION AND PRESERVED HIGH FREQUENCY HEARING IN A CASE OF PARTIAL DEAFNESS: POSSIBLE EXPANSION OF CI CANDIDACY

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B Data collection/entry
C Data analysis/statistics
D Data interpretation
E Preparation of manuscript
F Literature analysis/search
G Funds collection

Abstract

Introduction: Thanks to ongoing advancements in cochlear implant (CI) technology and surgical techniques, the eligibility criteria for CIs have expanded to include patients with various levels of low-frequency hearing. However, there is another group of patients with non-functional (or borderline functional) hearing at low frequencies but preserved residual hearing in the high-frequency range, thus making them off-label for a CI even though they get limited benefit from a hearing aid.

Case report: This study presents a 47-year-old patient with residual hearing at the functional border (75 dB HL or better) for low and mid frequencies (125–1500 Hz) and functional residual hearing (70 dB HL or better) for high frequencies (2000–8000 Hz). CI surgery was performed using the Med-El Flex26 electrode via round window insertion. Hearing preservation (HP) was complete up to at least 24 months and partial up to 36 months. For the high-frequencies only (2000–8000 Hz) there was complete HP for the entire 36 months. At 12 months post-surgery, the patient's word recognition scores (WRS) had improved by 75 percentage points in quiet and 70 points in noise.

Conclusions: The patient's results demonstrate that preserving functional residual hearing in the basal cochlea is possible after CI surgery, even though this region is very susceptible to insertion trauma. The presence of functional high-frequency hearing should not be the only reason for withholding CI surgery, especially if a hearing aid is ineffective.

Keywords: cochlear implant • partial deafness treatment • round window insertion • hearing preservation • electrode insertion trauma

STYMULACJA ZA POŚREDNICTWEM IMPLANTU ŚLIMAKOWEGO W ZAKRESIE NISKICH CZĘSTOTLIWOŚCI I ZACHOWANEGO SŁUCHU WYSOKOCZĘSTOTLIWOŚCIOWEGO W PRZYPADKU CZĘŚCIOWEJ GŁUCHOTY: MOŻLIWE ROZSZERZENIE WSKAZAŃ DO IMPLANTU ŚLIMAKOWEGO

Streszczenie

Wprowadzenie: Dzięki stałemu postępowi w technologii implantów ślimakowych oraz technik chirurgicznych kryteria kwalifikacji do wszczepienia implantu ślimakowego uległy rozszerzeniu i obecnie obejmują pacjentów z różnym stopniem zachowanego słuchu w zakresie niskich częstotliwości. Istnieje jednak grupa pacjentów z niefunkcjonalnymi resztkami słuchu (lub resztkami słuchu na granicy funkcjonalności) w zakresie niskich częstotliwości, przy jednoczesnym zachowaniu funkcjonalnych resztek słuchu w zakresie wysokich częstotliwości. Pacjenci ci

pozostają poza aktualnymi wskazaniami audiologicznymi do wszczepienia implantu ślimakowego, pomimo ograniczonych korzyści słuchowych ze stosowania aparatów słuchowych.

Opis przypadku: W pracy przedstawiono przypadek 47-letniego pacjenta z resztkowym słuchem na granicy funkcjonalności (≤75 dB HL) dla niskich i średnich częstotliwości (125–1500 Hz) oraz funkcjonalnymi resztkami słuchu (≤70 dB HL) dla wysokich częstotliwości (2000–8000 Hz). Procedurę wszczepienia implantu ślimakowego przeprowadzono z użyciem elektrody Med-El Flex26, stosując dostęp przez okienko okrągłe. Uzyskano całkowite zachowanie słuchu (*hearing preservation*, HP) do 24 miesięcy po operacji oraz częściowe zachowanie słuchu do 36 miesięcy obserwacji. W zakresie wyłącznie wysokich częstotliwości (2000–8000 Hz) odnotowano całkowite zachowanie słuchu przez cały 36-miesięczny okres obserwacji. Po 12 miesiącach od zabiegu wyniki rozpoznawania słów (word recognition scores, WRS) poprawiły się o 75 punktów procentowych w ciszy oraz o 70 punktów procentowych w szumie.

Wnioski: Uzyskane wyniki wskazują, że zachowanie funkcjonalnych resztek słuchu w podstawnej części ślimaka jest możliwe po implantacji ślimakowej, chociaż obszar ten jest najbardziej podatny na uraz związany z insercją elektrody. Obecność funkcjonalnych resztek słuchu w zakresie wysokich częstotliwości nie powinna stanowić jedynego powodu do wykluczenia pacjenta z kwalifikacji do wszczepienia implantu ślimakowego, szczególnie w przypadku, gdy aparaty słuchowe są nieskuteczne.

Słowa kluczowe: implant ślimakowy • leczenie częściowej głuchoty • insercja przez okienko okrągłe • zachowanie słuchu • uraz ślimaka związany z insercją elektrody

Key to abbreviations	
AC	air-conduction
BC	bone-conduction
BIAP	International Bureau of Audiophonology
CI	cochlear implant
CT	computed tomography
ENS	electro-natural stimulation
ESPCI	European Symposium on Paediatric Cochlear Implantation
HP	hearing preservation
PDT-EAS	Partial Deafness Treatment–Electro-Acoustic Stimulation
PDT-EC	Partial Deafness Treatment–Electric Complementation
PDT-ES	Partial Deafness Treatment–Electric Stimulation
PTA	pure-tone average
SNHL	sensorineural hearing loss
SRA	Straight Research Array
WRS	word recognition scores

Introduction

The term "cochlear implant" (CI) was first introduced into the medical literature in 1973 during an international conference in San Francisco on the use of electrical stimulation of the cochlear nerve to treat deafness in humans [1,2]. (Incidentally, that conference was attended by Blair Simmons, Robert White, William House, Jack Urban, and Claude Henri Chouard.) Not long afterwards, cochlear implantation became a standard procedure for treating deafness [3,4].

In Poland, the first cochlear implantation surgery was performed by Henryk Skarzynski in 1992 [5] and the technique has since given hope to thousands of deaf children and adults in the country. The positive results achieved in cases of complete deafness encouraged scientists and clinicians to gradually expand the indications for CI surgery in individuals with some residual hearing (referred to at the time as "non-functional" hearing).

The initial group included patients with preserved but non-functional residual hearing (Partial Deafness Treatment–Electric Stimulation, PDT-ES). Another group comprised patients with residual low-frequency hearing needing combined electro-acoustic stimulation, referred to as Partial Deafness Treatment–Electro-Acoustic Stimulation (PDT-EAS). In 2002, indications for cochlear implantation were expanded to adults with partial deafness [6], and in 2004, to children [7]. This included patients with Partial Deafness Treatment–Electric Complementation (PDT-EC), who had normal or nearly normal low-frequency hearing (up to 500 Hz) but required electrical stimulation for mid and high frequencies. Finally, indications were extended to patients with fully functional hearing in the 125–1500 Hz range but deafness at other frequencies, classified as electro-natural stimulation (ENS) [8,9].

All CI procedures in PDT treatment are based on a minimally invasive surgical approach, referred to earlier as the 6-step Skarzynski procedure, which involves inserting the electrode through the round window into the scala tympani [10]. Further development of PDT using CIs was also made possible by advances in technology, including the creation of delicate, flexible electrodes of varying lengths [11]. Since 1997, we have mostly used the Med-El system with flexible electrodes, including the Flex20, Flex24, Medium, and Flex28. In 2009, during the 9th European Symposium on Paediatric Cochlear Implantation (ESPCI) in Warsaw, Skarzynski performed the first demonstration operation using the Cochlear Nucleus Straight Research Array (SRA) electrode, developed according to his concept [12,13]. Subsequently, the next-generation Cochlear electrodes (422, 522, 622) have been used. Since 2017, the Advanced Bionics HiFocus SlimJ electrode has also been used in PDT [14]. Additionally, the Neuro Zti Oticon electrode has been used exclusively for patients diagnosed with minimally functional residual hearing prior to surgery [15].

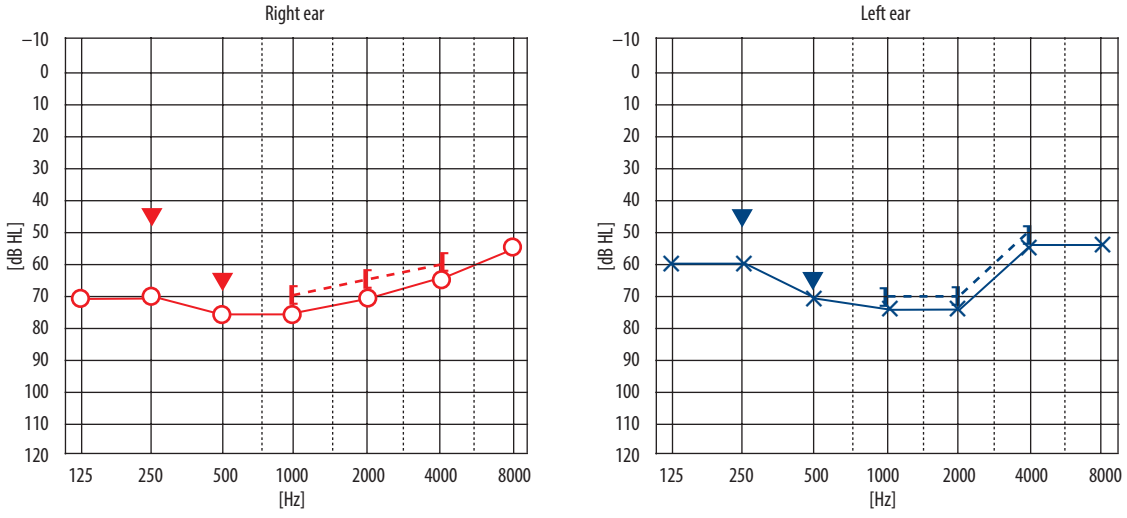

Figure 1. Patient's preoperative pure-tone audiometry for the right and left ears

Worldwide, similar procedures aimed at preserving residual hearing have also been carried out at other centers. However, the level of functional residual hearing varies among clinicians [16–23].

New electrodes of novel designs and varying lengths have been particularly successful in patients with high-frequency hearing loss (a "ski-slope" audiogram). At the same time, they have led to fresh challenges in everyday clinical practice, since they expand the current surgical indications and options. One notable new scenario, and the focus of this report, is called Partial Deafness Treatment–Low Frequency Stimulation. This type of hearing loss can, in a sense, be considered the 'reverse' of the typical partial deafness, since such patients have non-functional (or borderline functional) hearing in the low-frequency range but have preserved residual hearing in the high-frequency range. Traditionally, to preserve hearing at high frequencies, the management of this kind of partial deafness has generally involved the use of multichannel hearing aids; however, they often result in limited effectiveness in terms of speech understanding.

It now appears that a CI can effectively work in this scenario. This paper reports the effectiveness of a CI, including a measure of HP outcome, in a patient with preoperative functional residual hearing in the high-frequency range.

Case report

A 47-year-old patient with bilateral, sensorineural hearing loss (SNHL) first presented to the Oto-Rhino-Laryngology Surgery Clinic at our center in 2018. During the medical interview, it was noted that at age 40, the patient experienced his first episode of sudden SNHL in the right ear, accompanied by severe tinnitus and vertigo. Despite hospitalization and intravenous dexamethasone treatment, the hearing loss in the right ear progressed slowly and gradually At age 46, the patient experienced another episode of bilateral sudden SNHL with vertigo. Despite hospitalization and treatment, which included oral steroids, intratympanic steroid injections via a drain, and hyperbaric oxygen therapy, no hearing improvement was achieved. The patient had been using hearing aids bilaterally, although irregularly, due to limited effectiveness. The patient has not undergone genetic testing.

Preoperative audiometric evaluation

Pure-tone audiometry was performed to assess air-conduction (AC) thresholds at 125–8000 Hz, and bone-conduction (BC) thresholds at 250–4000 Hz, in accordance with clinical standards (ISO 8253-1: 2010) [24]. Results of preoperative pure-tone audiometry are presented in **Figure 1**. The pure-tone average (PTA) for AC at frequencies of 500, 1000, 2000, and 4000 Hz was 71.2 dB HL for the right ear and 68.8 dB HL for the left. According to the classification of hearing loss proposed by the International Bureau of Audiophonology (BIAP) [25], the patient's hearing loss was classified as severe in the right ear and moderate in the left. For this reason, the right ear was classified as suitable for CI surgery. Preoperative hearing thresholds in the right ear were 75 dB or better for low and medium frequencies (125–1500 Hz), while for high frequencies (2000–8000 Hz) they were 70 dB HL or better.

Surgical procedure

In March 2021, the patient underwent CI surgery. To protect the delicate structures of the inner ear and, specifically, to preserve residual hearing at low frequencies, which were on the border of functional hearing, the decision was made to use a flexible electrode array from Med-El (GmbH, Innsbruck, Austria). Based on preoperative computed tomography (CT) images of the temporal bone and Med-El's Otoplan tool (**Figure 2**), the Flex26 electrode was selected. Virtual 3D scala tympani insertion analysis revealed that the 26 mm electrode array had a high likelihood of providing complete cochlear coverage across the full range of cochlear duct lengths, with a cochlear angle of 475° corresponding to a frequency of 521 Hz. The surgical procedure was performed by the senior surgeon

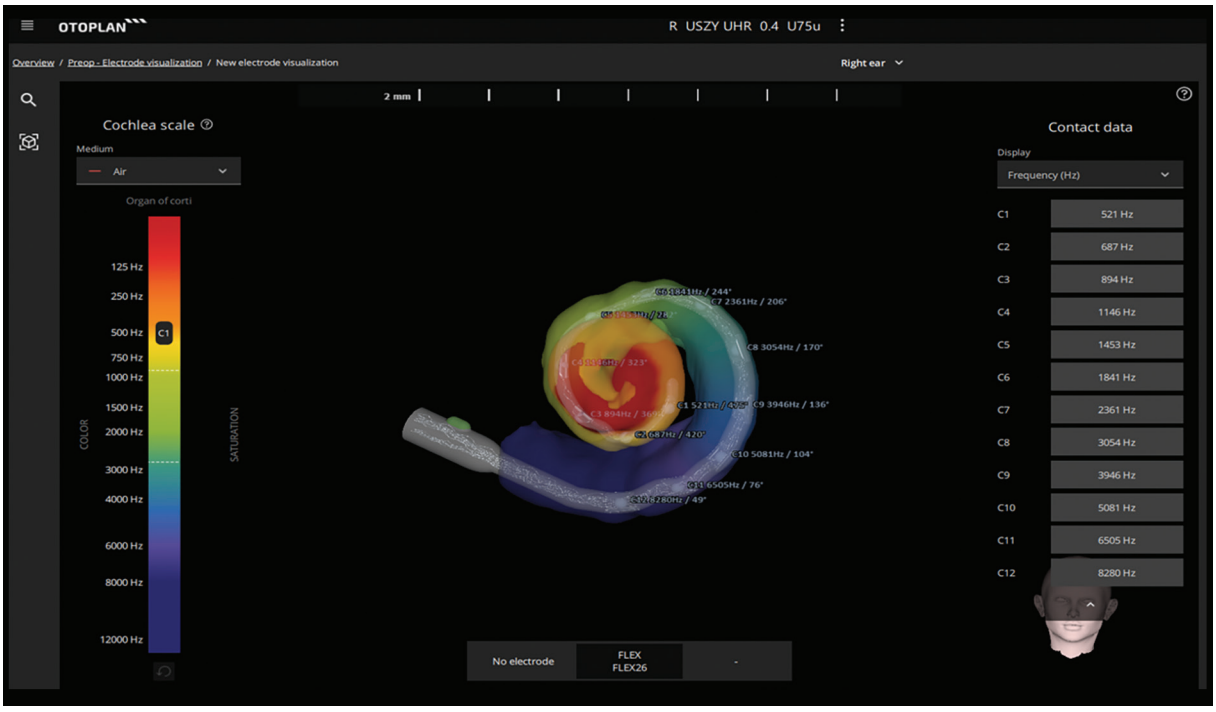

Figure 2. Preoperative visualization of the patient's cochlea and insertion of the Med-El Flex26 electrode, based on Med-El's Otoplan

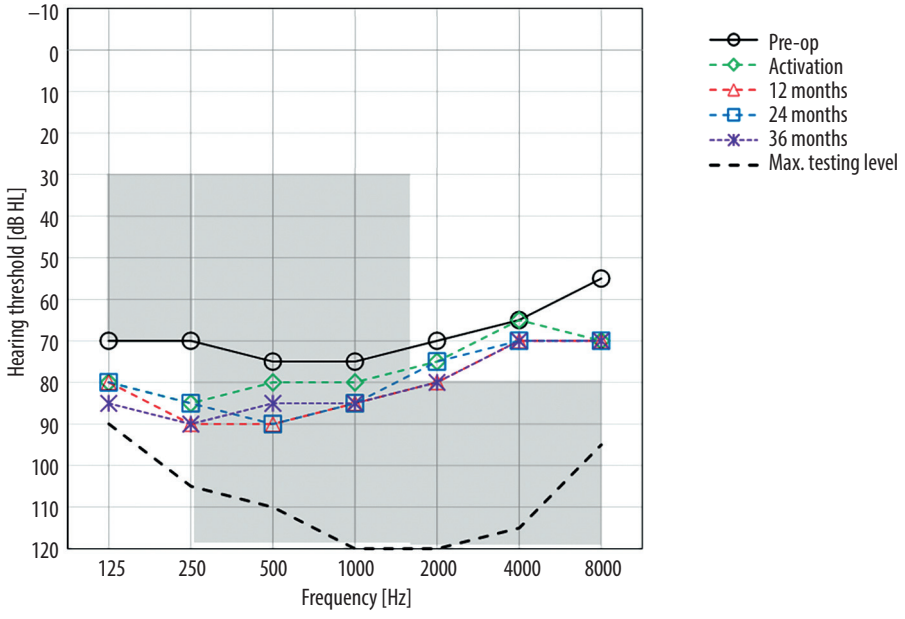

Figure 3. Pre- and postoperative air conduction hearing thresholds for the implanted ear. The shaded area represents the range of indications for electro-acoustic stimulation according to Skarzynski's concept

(the first author of this paper). A minimally invasive round-window approach, following the Skarzynski six-step procedure [10] was used, with full insertion of the CI electrode. Steroid (dexamethasone) was administered to the patient according to the procedure previously described by Skarzynska et al. [26].

Postoperative audiometric evaluation

Postoperative pure-tone audiometry was performed 1 month after surgery (at activation), and subsequently at 12, 24, and 36 months. The pre- and postoperative AC thresholds for the operated ear are shown in **Figure 3**.

Before surgery, the mean AC threshold at all tested frequencies was 68.5 dB HL. At activation, the mean AC thresholds increased by 8.1 dB HL. In the longer postoperative follow-up periods (i.e., 12, 24, and 36 months), the mean AC thresholds increased, with the maximum shift being 12 dB HL compared to preoperative values. When analyzing only the high-frequency range (at 2, 3, 4, 6, and 8 kHz), the mean preoperative AC thresholds were

Table 1. Results of hearing preservation according to Skarzynski's HP classification

Postoperative follow-up	Hearing preservation [%]	Evaluation
1 month	85.4	Complete HP
12 months	75.3	Complete HP
24 months	78.7	Complete HP
36 months	74.2	Partial HP
Key		
S	**Evaluation**	
> 75%	Complete HP	
26–75%	Partial HP	
1–25%	Minimal HP	
No detectable hearing	Loss of hearing	

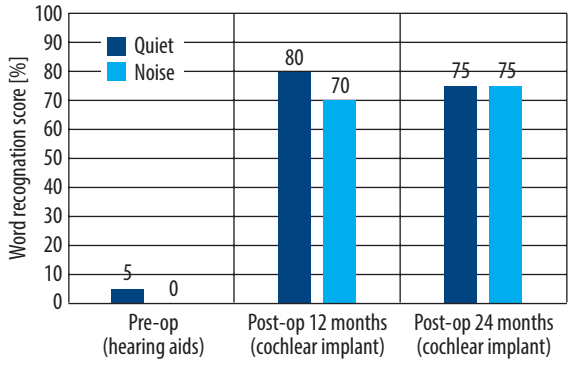

Figure 4. Word recognition scores in quiet and noise, before and after cochlear implantation

63.5 dB HL. During activation, the mean high-frequency AC thresholds increased by 6.5 dB HL. In the longer postoperative follow-up periods (i.e., 12, 24, and 36 months), the mean high-frequency AC thresholds increased, with the maximum shift being 9.5 dB HL compared to preoperative values.

Hearing preservation evaluation

The HP classification system proposed by Skarzynski et al. [27], based on preoperative and postoperative pure-tone audiometry thresholds (including 11 audiometric frequencies), was used to calculate HP. Hearing thresholds were measured five times: preoperatively, 1 month after surgery (at activation), 12 months post-surgery, 24 months post-surgery, and 36 months post-surgery. The exact HP values (S values) obtained for the patient are presented in **Table 1**. Calculating the percentage change in hearing thresholds postoperatively according to this HP classification showed that hearing was completely preserved up to 24 months post-surgery and partially preserved up to 36 months post-surgery.

Additionally, HP was assessed separately for high frequencies (at 2, 3, 4, 6, and 8 kHz). After surgery, the calculated S-value at the 1-month follow-up was 86%, at 12 months it was 81.7%, at 24 months 83.9%, and at 36 months 79.6%. These results indicate complete HP throughout the postoperative follow-up period.

Speech discrimination evaluation

The Demenko & Pruszewicz Polish Monosyllabic Word test [28] was used to assess the word recognition score (WRS) in free field at 65 dB SPL. Prior to surgery, the test was conducted with a fitted hearing aid in both quiet and noisy conditions (at a signal-to-noise ratio of +10 dB). To assess speech recognition gain, the WRS with the CI processor was performed 12 and 24 months post-surgery. The WRS results (**Figure 4**) show that over a period of 12 months, speech recognition improved from 5% to 80% in quiet and from 0% to 70% in noise. These improvements remained stable throughout the 24-month postoperative follow-up.

Discussion

The insertion of an electrode array during CI surgery often causes trauma to the cochlea, leading to ganglion cell death, necrosis, and apoptosis [29,30]. For patients with residual acoustic hearing, preserving both the residual hearing and the structural integrity of the cochlea during and after CI surgery is crucial to improving hearing outcomes [31]. CI users with residual low-frequency hearing exhibit better speech understanding, particularly in challenging listening conditions [32]. The design of the electrode array, including its length, is crucial in minimizing trauma during surgery [33]. While shallow electrode insertions may help preserve apical organ of Corti structures, the extent of trauma to the basal cochlea during insertion remains unclear.

This paper reports what is thought to be the first results of an adult patient with partial deafness and functional residual high-frequency hearing who underwent cochlear implantation. The etiology of his sudden hearing loss could not be determined; however, a genetic contribution cannot be excluded. Phenotypic analysis using AudioGene software [34] indicated that the patient's audiogram most closely matches the hearing loss pattern associated with pathogenic variants in the *WFS1* gene, which is typically linked to autosomal dominant low-frequency sensorineural hearing loss. The characteristic audiometric profile – marked by the largest threshold deterioration at low and mid frequencies, with relatively preserved hearing above 4 kHz – is consistent with the described phenotype of this gene. Additional loci suggested by the analysis, CCDC50 and MYO7A, may also contribute to autosomal dominant forms of hearing loss; however, their associated phenotypes generally involve higher frequencies or demonstrate greater progression. The resulting gene ranking supports the prioritization of *WFS1* in molecular diagnostic testing, which may carry both prognostic value and implications for clinical management and genetic counseling.

Although hearing aids are typically recommended for residual high-frequency hearing, their benefits can be limited, which supports the decision to proceed with cochlear

implantation [35]. Audiograms alone may not reveal cochlear dysfunction, as dead regions in outer and inner hair cells can limit hearing aid effectiveness [36]. Vinay et al. [37] found dead regions in 59% of ears with SNHL, especially at frequencies above 70 dB HL. This may explain the low WRS outcomes observed in our patient, which were not consistent with their hearing thresholds. Cochlear implantation was the only viable option to restore effective hearing. After 12 months, the patient showed significant improvement in speech recognition, with a 75 percentage point increase in quiet and 70 points in noise. The decision to use a 26 mm electrode array was made to minimize intracochlear trauma during implantation, especially at low frequencies (up to 500 Hz), where the patient's preoperative hearing was on the borderline of functional residual hearing.

The Flex26 is the newest lateral-wall electrode array developed by Med-El, having a length between their medium and long arrays [38]. It offers the same active stimulation range (20.9 mm) as the shorter Flex24 but provides greater angular insertion depth [39]. Ketterer et al. [40] reported that the insertion angle of the Flex26 ranged from 377° to 601°, with a mean of 517° (*SD* 60°), showing no displacement from scala tympani. In contrast, displacement was observed with longer electrodes, such as the FlexSoft and Flex28. Other studies have shown that the insertion angle depends not only on electrode array type but also cochlear length [41,42]. Timm et al. [43] recommend incorporating preoperative cochlear length assessment into routine care due to cochlear size variations. Additionally, interventions like steroids or intraoperative electrocochleography [30] can further improve HP. In our patient, preoperative CT imaging and the Otoplan tool predicted that the Flex26 electrode would provide cochlear coverage and full electrode placement in the scala tympani up to 521 Hz. Low-frequency HP was crucial, as we expected potential loss of residual high-frequency hearing due to insertion trauma. However, at the 24-month postoperative follow-up, HP was complete, and at 36 months there was only a slight deterioration, mainly in low-frequency thresholds. High-frequency HP remained intact throughout the 36-month observation period, indicating that full electrode insertion had not affected HP.

In our center, for many years we have preferred the round window approach surgical technique. According to Dhanasingh and Jolly [44], an atraumatic insertion depends on surgical technique, electrode array design, cochlear duct length, anatomical variations, insertion angle, and cochlear height. In a histological analysis of 33 temporal bones using Med-El electrodes, Adunka et al. [45] identified two mechanisms of basal trauma: array buckling and trauma from drilling. They found that the caudal approach (cochleostomy) led to 48% destructive basal trauma, compared to less than 15% with round window insertions. Recent studies have shown growing interest in biomarkers such as impedance telemetry, which measures inner ear events such as impedance spikes [31]. Gu et al. [46] found that electrodes implanted via the round window approach showed significantly lower impedance than those implanted with the traditional cochleostomy method, particularly at the cochlear base. The authors emphasise that the use of an atraumatic surgical approach probably helps in preserving cochlear architecture and preventing cochlear fibrosis.

To our knowledge, this is the first reported case in which pre-operative high-frequency hearing was assessed following cochlear implantation. The study's limitations should be acknowledged, arising from its retrospective design and the analysis being limited to a single patient. Further systematic investigations involving a larger group of patients with this type of partial deafness are needed to better understand the potential for preserving residual hearing following surgery.

Conclusions

Our patient's results demonstrate that preserving functional residual hearing in the basal cochlea is possible after CI surgery, even though this region is most susceptible to insertion trauma. The presence of functional high-frequency hearing should not be a major reason for withholding cochlear implantation, especially if a hearing aid is ineffective. Larger studies are needed to assess the potential for expanding CI candidacy in patients with this type of partial deafness.

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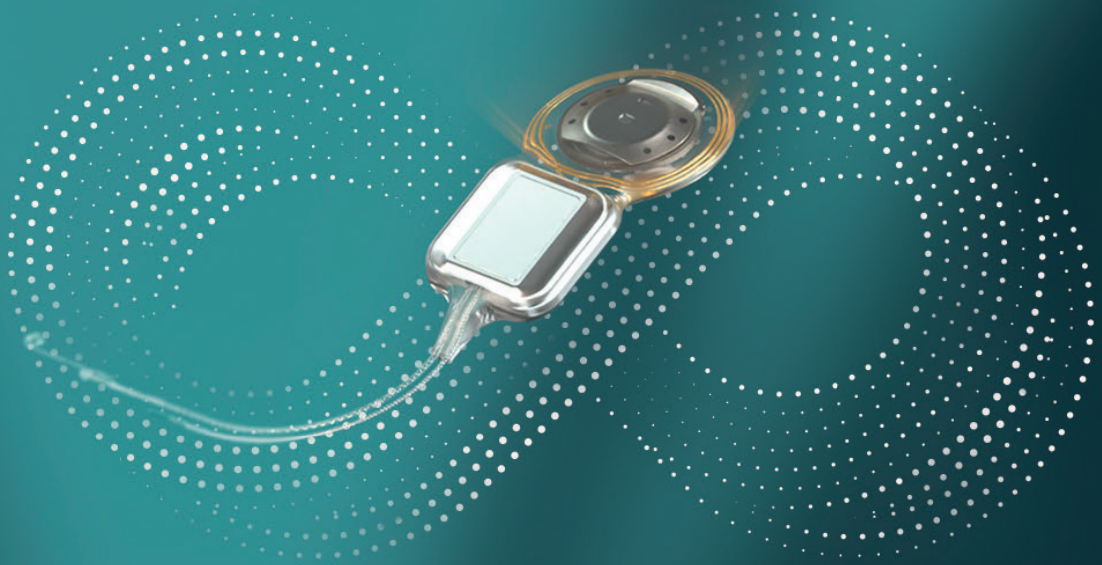

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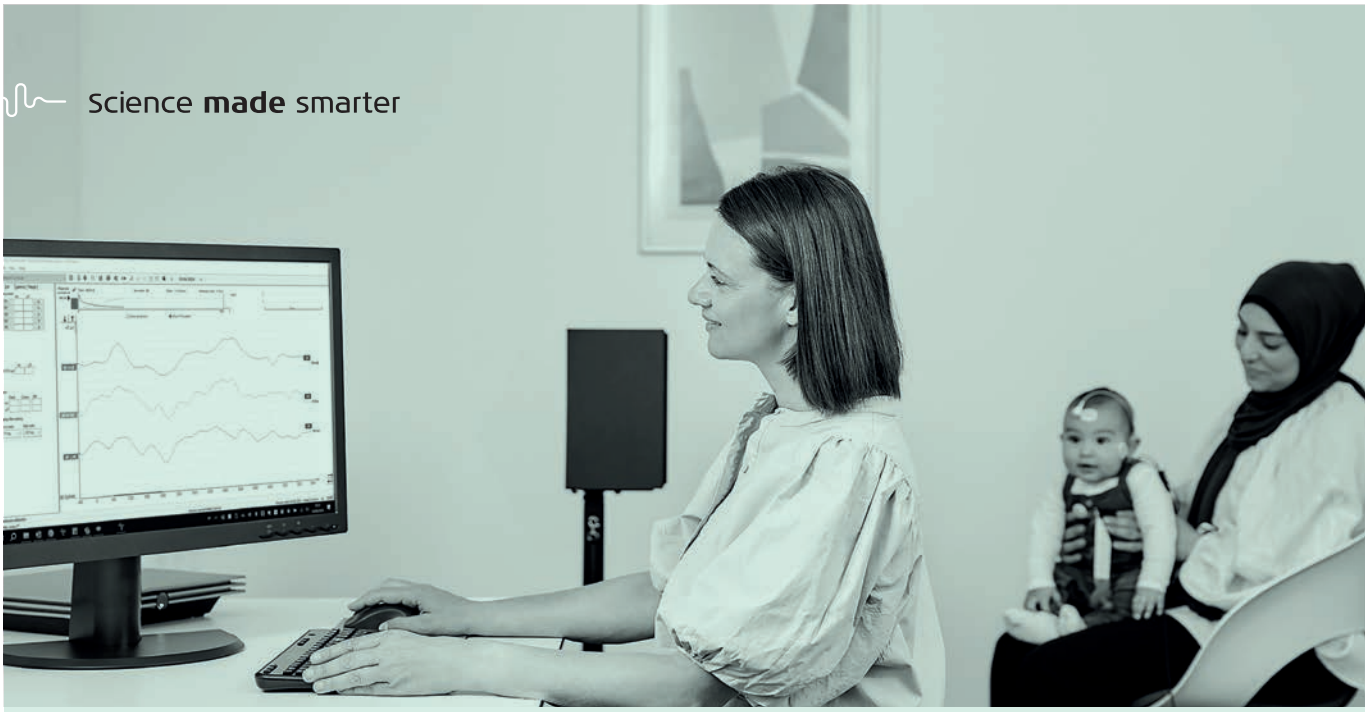

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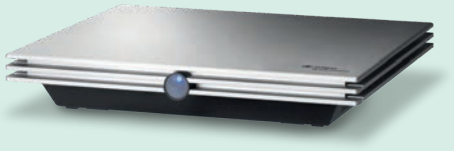

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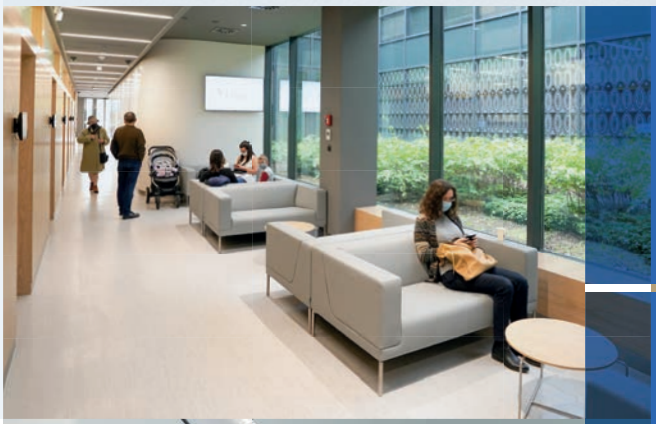

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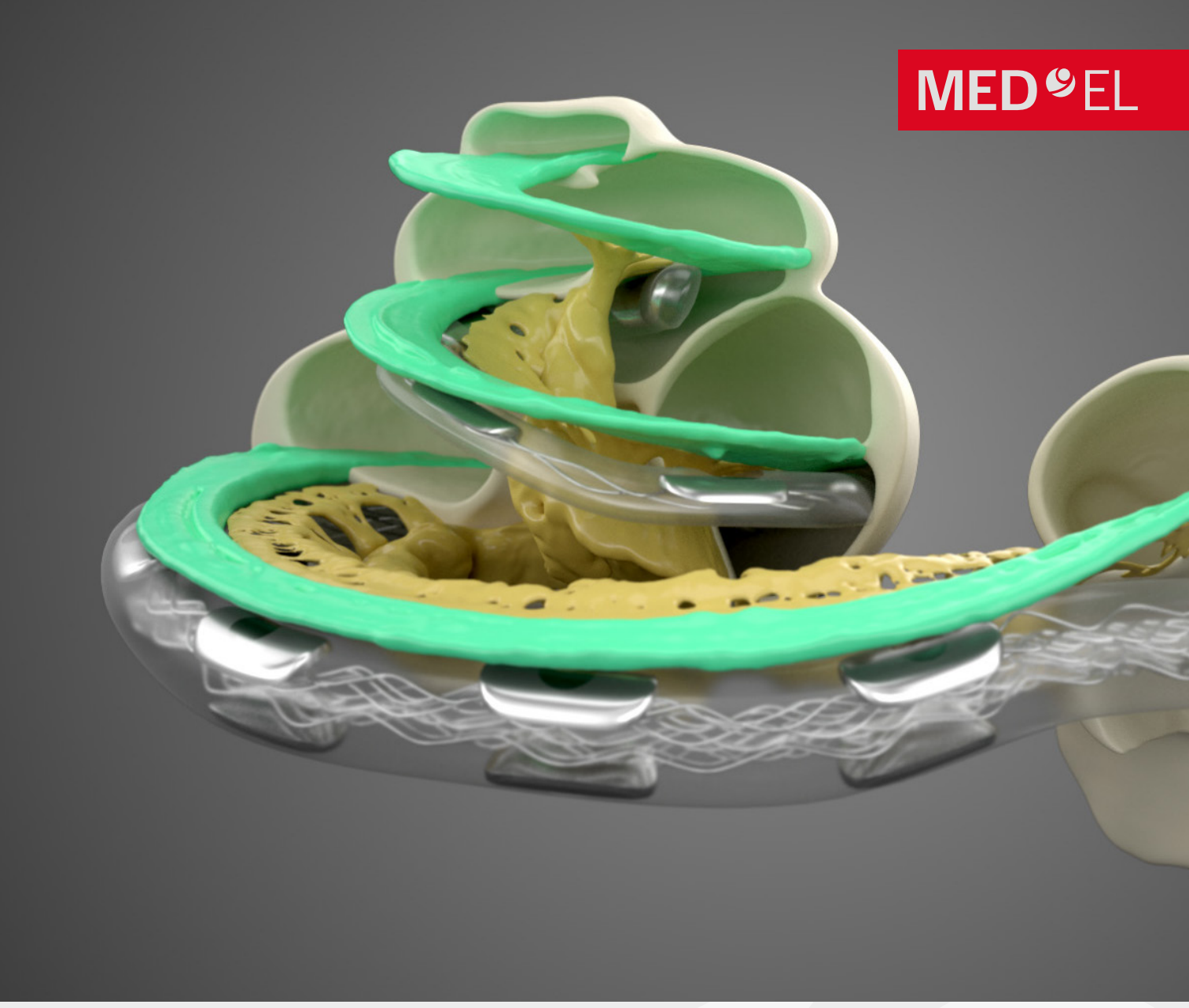

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