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Reduced tinnitus impact using Oticon hearing aids equipped with Tinnitus SoundSupport™

ABSTRACT

Tinnitus affects millions of people throughout the world in vastly different ways. A clinical understanding of risk factors and the various theoretical models of tinnitus can be beneficial when tailoring individualized treatment plans for patients. This paper will first describe current commonly used methods for tinnitus management including sound therapy, counseling, and cognitive behavioral therapy. An overview of Oticon Tinnitus SoundSupport™ follows, including the Comfort pulse feature in the Oticon Companion app. This paper then concludes with a brief review of the latest evidence displaying the benefit of Oticon hearing aids equipped with Tinnitus SoundSupport™ for new and experienced hearing aid users.

EDITOR OF ISSUE

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Introduction

Tinnitus is defined as the perception of sound without any external auditory source present. Roughly 30% of people will experience tinnitus during their lifetime (Mancktelow, 2024). Recent studies have found that at least 740 million people in the world experience tinnitus, with more than 120 million of these suffering severe symptoms (Jarach et al., 2022). Similarly, another study found that more severe cases of tinnitus can significantly disrupt quality of life for 10-20% of tinnitus patients (Langguth et al., 2024), leading to challenges such as anxiety, depression, altered auditory perception, and sleep disturbance (Yang et al., 2024).

Tinnitus manifests differently for everyone. Patients may describe it as ringing, buzzing, hissing, whistling, chirping, or roaring. Approximately 45% of people perceive tinnitus unilaterally, 45% bilaterally, and roughly 10% report it as non-lateralized (Langguth et al., 2024). Just as the presentation of tinnitus is unique for each patient, so is its intensity, severity, and frequency. Patients may describe it as barely audible and intermittent on some days, whereas it may be perceived as a constant, loud sound on others.

The subjective nature of tinnitus has made standardization of clinical management difficult. However, this paper serves to review the most commonly used clinical tools that can be utilized to support patients in managing their tinnitus as well as highlight results from a partner study that demonstrates the effectiveness of Oticon hearing aids (HAs) programmed with Tinnitus SoundSupport™ (TSS).

Risk factors associated with tinnitus

- Occupational, recreational, and/or transient noise exposure
- Hearing loss
- Stress
- Depression
- Smoking
- Osteoarthritis
- Rheumatoid arthritis
- Thyroid disease
- Hyperlipidemia
- Asthma
- Ototoxic medications (e.g., platinum-based therapies)
- Otitis media
- Chronic obstructive pulmonary disease
- Temporomandibular joint disorder

(Kim et al., 2015; Biswas et al., 2023)

Clinical assessment & management of tinnitus

It is not uncommon for clinicians to encounter patients with co-occurring tinnitus and hearing loss, as hearing loss is observed in approximately 90% of tinnitus cases (Hearing Health Foundation, 2024). Clinically, a comprehensive case history as well as pure-tone and speech audiometry are frequently used to evaluate tinnitus. Many clinicians have also employed the use of questionnaires like the Tinnitus Functional Index (TFI) (Meikle et al., 2012) and Tinnitus Handicap Inventory (THI) (Newman et al., 1996) to gain insight into how tinnitus impacts quality of life as well as perceived consequences of tinnitus.

Did you know?

Tinnitus is usually categorized in one of two ways:

- **Subjective – can only be perceived by the person experiencing it, and accounts for most cases encountered in the clinic. It can manifest as buzzing, hissing, ringing, etc.**
- **Objective – caused by an underlying etiology that can be observed by another party, like the presence of stapedial myoclonus, or muscle spasm of the stapedial tendon within the middle ear space (Vasilescu & Weisman, 2023; Barber et al., 2020). Objective tinnitus is seldom encountered compared to subjective tinnitus.**

The underlying mechanisms of tinnitus are not precisely understood. Here is a brief overview of some of the models that aim to describe the pathophysiology of tinnitus:

- **Peripheral Model** – peripheral auditory dysfunction leads to spontaneous neuronal activity which the brain subsequently perceives as sound
- **Central Model** – reduced auditory stimuli alter central auditory pathways leading to spontaneous neuronal activity and possible imbalances with neurotransmitters
- **Gating Model** – undesirable and/or repetitive auditory stimuli is perceived as tinnitus by the auditory cortex due to limbic system deficits that would otherwise inhibit unnecessary auditory input
- **Somatosensory Model** – atypical interactions between the auditory and somatosensory systems create an increase in neuronal activity within central auditory pathways
- **Inflammatory Model** – neuroinflammation resulting from noise exposure and/or hearing loss leads to an excitation-inhibition imbalance that is perceived as tinnitus

(Langguth et al., 2024; Singh et al., 2023; Adcock & Vanneste, 2022)

Other methods of assessment include distortion product otoacoustic emissions (DPOAEs), auditory brainstem response (ABR), minimal masking levels (MMLs), and pitch/loudness matching (Park et al., 2022).

Clinical management of tinnitus encompasses a wide array of approaches including counseling, cognitive behavioral therapy (CBT), sound therapy, amplification using HAs, cochlear implantation, tinnitus retraining therapy (TRT), Progressive Tinnitus Management (PTM), auditory perceptual training, pharmacological intervention, and neuromodulation.
The various approaches to tinnitus intervention can be used in isolation or as complementary to one another. It is crucial for clinicians to be aware of and appropriately offer various treatment options, so that intervention can be tailored to each patient's specific needs and goals. Clinicians should also maintain flexibility in their approach to tinnitus treatment, as symptoms can fluctuate over time. The following sections of this paper will focus on some of the existing clinical management approaches to tinnitus including sound therapy, counseling and cognitive behavioral therapy.

Sound therapy

Patients with tinnitus and hearing Loss

Sound therapy is widely recognized by clinicians as a non-invasive, straightforward method to mask the tinnitus or promote habituation to the tinnitus. This technique promotes cortical reorganization that allows for temporary tinnitus relief during acoustic stimulation (Wang et al., 2020). In addition to the partner study discussed in this paper (Sanders et al., 2023), there is much evidence to support that sound therapy combined with HAs (i.e., combination devices) is beneficial for patients with hearing loss and bothersome tinnitus (Ganesan et al., 2021; Bauer, 2018).

Patients with tinnitus and normal hearing

While less common, clinicians may encounter patients who exhibit tinnitus without hearing loss. A study by Davidson and colleagues (2024) found low-gain prescription HAs to be beneficial for military service members with normal hearing thresholds that self-reported tinnitus and difficulty understanding speech in noise. Sometimes HAs containing sound therapy alone is enough to alleviate tinnitus, as seen in a study by Rocha et al. (2016). This study observed a reduction in THI scores for normal-hearing participants with tinnitus after being fit with hearing aids that contained sound generation without amplification. Interestingly, Vasilkov and colleagues (2023) found that participants with normal hearing that self-reported chronic tinnitus were associated with cochlear neural degeneration and hyperactivity in central auditory pathways. Cochlear

neural degeneration has been hypothesized as a contributing factor to degraded speech understanding in noise. (Vasilkov et al., 2023). This predicament also manifests in patients with normal audiometric thresholds and chronic tinnitus.

These findings support the use of low-gain amplification and/or sound generator programs as viable treatment options for patients with normal hearing thresholds and tinnitus. Additionally, these interventions may promote favorable outcomes for this population if difficulty understanding speech in noise is also of concern.

Managing tinnitus with Oticon's Tinnitus SoundSupport™

Tinnitus SoundSupport™ (TSS), Oticon's proprietary tinnitus sound generator, has been used as a clinical management tool with tinnitus patients for the last decade (Løve, 2014). TSS serves to effectively mask and promote habituation to tinnitus so patients may experience relief from their symptoms while using HAs.

Due to the subjective nature of tinnitus, the way in which and to what extent the perception of it can be effectively masked and habituated to differs for each patient. TSS is highly customizable for this reason. There are options to select from differently shaped broadband noises, including shaped to audiogram, white, pink and red noise, in the Oticon Genie 2 fitting software. The broadband noises can also be customized in terms of modulation. The following options currently exist in Genie 2, ordered from zero to maximum modulation: "Off", "Tranquil", "Mild", "Spirited", and "Bustling". Alternatively, preset amplitude-modulated forms of the broadband noises are also available to represent more naturalistic sounds. These are labeled as Ocean 1, Ocean 2, and Ocean 3.

The selected sound can be customized by adjusting both the volume and audible frequency range to meet the unique needs of each patient. This can aid patients in finding effective, non-distracting sound stimulation to alleviate their tinnitus. Multiple tinnitus programs may serve as an effective intervention for patients who often report fluctuations in their symptoms, as this allows them to access both steady-state and amplitude-modulated noise.

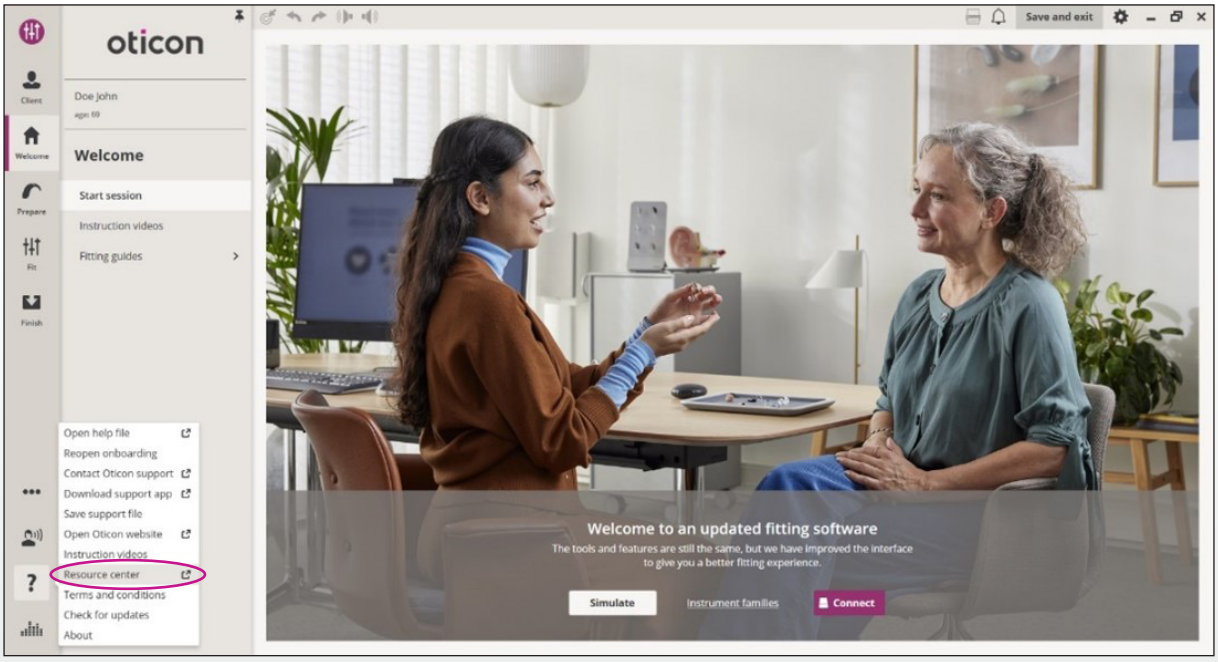

Figure 1. Screenshot in Genie 2.

Finally, the Tinnitus SoundSupport™ Fitting Checklist and other tinnitus-related tools can be found in the Resource Center located on the left-hand panel that is available in Genie 2 (see Figure 1). Oticon has tools that aid hearing care professionals in providing person-centered care throughout tinnitus intervention, from the initial tinnitus consultation to subsequent follow-up appointments.

Oticon Companion app allows for customization of tinnitus masker

The Oticon Companion app includes the Comfort pulse feature (see Figure 2). Comfort pulse allows patients to choose the modulation speed of their tinnitus masker. This feature allows patients to actively participate in their treatment plan and allows them to personalize their masker to account for daily fluctuations in tinnitus. Note that Comfort pulse requires TSS to be activated in Genie 2 using a broadband sound with an existing degree of modulation (e.g., preset to "Tranquil", "Mild", "Spirited", or "Bustling").

When to activate Tinnitus SoundSupport™?

Categorization of tinnitus severity is multifaceted. While psychometric scales such as the TFI and THI exist to help quantify tinnitus impact, scores need to be taken into consideration alongside other patient information. If a patient exhibits bothersome tinnitus and other signs of distress, activation of TSS may be warranted. The creation of separate static and modulated TSS programs offers flexibility to account for fluctuations in tinnitus and can be programmed with higher levels of sound for especially bothersome tinnitus days. Continuous activation of TSS is not necessarily required throughout the day, but rather for however long is needed to provide individual relief. Tinnitus intervention is unique to each person. Providing both informational and support counseling throughout follow-up appointments is vital in strengthening patient outcomes.

Counseling

While sound therapy can be beneficial for managing tinnitus, another imperative aspect of intervention is counseling. Effective counseling can be attained by providing patients with pertinent and accurate information about tinnitus. Moreover, actively listening to patients while expressing empathy can help to develop rapport throughout intervention. There are multiple ways to counsel and offer useful intervention strategies. Recognizing that each person has unique needs and goals is also important when implementing counseling.

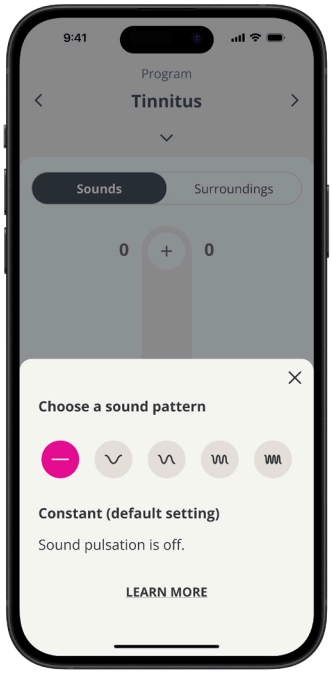

Figure 2. Screenshot of selecting modulation speed using the Comfort pulse feature in the Oticon Companion app.

Disclaimer: This feature is only available in the Oticon Companion app to communicate with HAs containing wireless technology. A Bluetooth® Low Energy connection is required for pairing to the patient's mobile device.

"Tinnitus intervention is unique to each person. Providing both informational and support counseling throughout follow-up appointments is vital in strengthening patient outcomes."

Cognitive behavioral therapy and referral to mental health providers

Historically, cognitive behavioral therapy (CBT) has fulfilled an instrumental role in many tinnitus rehabilitation programs, such as PTM designed by the National Center for Rehabilitative Auditory Research (NCRAR) in Portland, Oregon. CBT can be implemented by a mental healthcare provider, audiologist trained in CBT, or via an interdisciplinary approach (Miller, 2023).

The primary objective of CBT is habituation, where the goal is to decrease the negative emotional response associated with tinnitus through improvement of cognitive control and reduction in distressing behaviors (Langguth et al., 2024). Not all patients require implementation of CBT in their tinnitus intervention plan. However, it is important to recognize patients with highly elevated negative emotional reactions to tinnitus and consider referral to a mental health provider trained in CBT for tinnitus if needed. (Miller, 2023).

Research with Oticon hearing aids equipped with Tinnitus SoundSupport™

Purpose:

A partner study conducted with Sanders and colleagues (2023) at the University of Auckland in New Zealand aimed to analyze if Oticon HAs equipped with TSS would determine the impact of tinnitus in both new and experienced HA users over an intervention period of 12 weeks.

Participants:

40 participants with tinnitus were recruited by the University of Auckland Hearing & Tinnitus Clinic for this study. 21 participants were new hearing aid users and 19 had worn hearing aids in the past for six months or longer. Further information regarding the inclusion criteria of this study is outlined in Table 1:

• ≥ 18 years
• Chronic tinnitus (≥ 6 months post onset)
• Flat or sloping mixed or sensorineural hearing loss
• 60-dB or 85-dB receivers fit with domes or custom molds

Table 1. Age and audiologic information of participants.

Methods & materials

This study spanned 12 weeks, consisting of three total visits which are detailed below:

Visit 1: Screening, testing & HA fitting – Participants completed the following questionnaires: Tinnitus Sample Case History Questionnaire (TSCHQ), Depression Anxiety and Stress Scale-21 Items (DASS 21), Tinnitus Functional Index (TFI), Tinnitus Handicap Inventory (THI), Client Oriented Scale of Improvement on Tinnitus (COSIT), and a subjective tinnitus severity scale. Pure-tone audiometry from 250-8000 Hz and tinnitus pitch matching from 250-16000 Hz was administered for each participant. The first visit then concluded with a HA fitting using Oticon More™ HAs that were verified to match NAL-NL2 targets using REM. Each set of HAs contained four programs (see Table 2). Settings for programs B-D were counterbalanced between participants.

Program A	Amplification only with default settings
Program B	Amplification with enhanced noise reduction settings
Program C	Amplification with TSS activation
Program D	Amplification with enhanced noise reduction settings and TSS activation

Table 2. Hearing aid programs assigned to each participant.

Visit 2: Three-week follow-up – HA gain and TSS adjustments were completed based on participant feedback. At this time programs B-D were also reordered based on personal preference.

Visit 3: 12-week follow-up – The TFI, THI, DASS 21, COSIT and subjective severity scales were completed a second time by participants. Changes to the HA fitting and/or TSS settings were also completed based on participant feedback.

Results

The following section includes a portion of the results from the study. Details for all results can be found in Sanders et al., 2023.

TFI

The current study primarily utilized the TFI and THI as psychometric questionnaires to quantify tinnitus impact for each participant. The TFI included subscales which examined intrusiveness, sense of control, cognitive interference, sleep, auditory perceptual problems due to tinnitus, inability to relax due to tinnitus, quality of life, and emotional distress (Henry et al., 2016). Participant TFI scores were categorized based on severity: low (0-18), lower moderate (19-42), upper moderate (43-65), and high (66-100).

TFI scores for participants ranged from 12.4 to 85 points at baseline and ranged from 2.4 to 80 points at the 12-week follow-up appointment. The median total TFI score at baseline was 49 and reduced to 26 at the 12-week follow-up appointment (see Figure 3). A 47% reduction of tinnitus impact across all participants can be observed when comparing the total median baseline to median final TFI scores. A reduction in TFI score of at least 13 points is considered clinically meaningful (Meikle et al., 2012).

A statistically significant reduction in the total TFI score was observed at the final visit ($p < 0.0001$), demonstrating a shift from participant scores in the upper moderate category at baseline to lower moderate category at the final visit. Statistically significant reductions were also observed in all eight TFI subscales.

THI

The THI was scored based on participant severity: slight (0-16), mild (18-36), moderate (38-56), severe (58-76), and catastrophic (78-100). THI scores for participants ranged from 6 to 98 points at baseline and ranged from 2 to 82 points at the final follow-up visit. The median total THI score at baseline was 40 and reduced to 23 points at the final visit (see Figure 3).

Median total THI scores had a statistically significant reduction ($p < 0.0001$) of 17 points between baseline assessment and the final visit. A shift from participants scoring in the severe/catastrophic range to the slight/mild/moderate range was observed from baseline to the final visit.

COSIT

The COSIT was used to define the personal tinnitus-related goals of participants. An improvement of at least 50% from mean baseline to mean final score was observed for 78% of participants. Half of all participants reported improvement on 100% of their personal goals. The experienced HA users reported greater improvement over the 12-week intervention period compared to new HA users.

Hearing aid program usage

Table 3 outlines HA program usage across all participants, with (1) being the most widely used program and (4) being the least used.

Discussion

This study demonstrated a clear reduction on the impact of tinnitus for both new and experienced HA users fit with Oticon HAs equipped with TSS. The key findings of this study are outlined below:

1. **Reduction in TFI and THI scores:** This study demonstrated a clinically significant reduction in TFI scores from baseline to week 12 of intervention using Oticon HAs. A 47% reduction of tinnitus impact across

Program A (1)	Amplification only with default settings
Program C (2)	Amplification with TSS activation
Program D (3)	Amplification with enhanced noise reduction settings and TSS activation
Program B (4)	Amplification with enhanced noise reduction settings

*Table 3. Ordering of HA programs used by participants, with (1) denoting the most-used program and (4) denoting the least-used program. *Experienced users spent more time in Program A compared to new users.*

1. all participants can be observed when comparing median total baseline to median final TFI scores. The median total THI score of 40 points dropped to 23 points at the end of the intervention period.

2. **Shift to less severe categories:** As quantified by both TFI and THI scores, a shift from more severe to less severe categories was observed across all participants from baseline to the end of the intervention period.

3. **Benefit observed in new and experienced users:** The reduction observed in psychometric scores was similar for both new and experienced HA users.

4. **Personally meaningful improvements via the COSIT:** Most participants reported personally meaningful improvements at the end of the intervention period. This was quantified as at least 50% or more improvement on one or more personal goals. Experienced HA users reported more improvement at the end of the 12-week period compared to new HA users. This unexpected outcome may have resulted from more realistic expectations by the experienced HA group.

5. **HA program usage:** Program A, which consisted of amplification only with the prescribed default settings, was the most commonly used HA program in this study. However, an informal interview at the end of the intervention period revealed many participants reported they were not engaging in as many social events or adverse listening environments as they had been prior to the COVID-19 pandemic. This indicates that program use could have been reflected differently if participants found themselves in more complex listening situations.

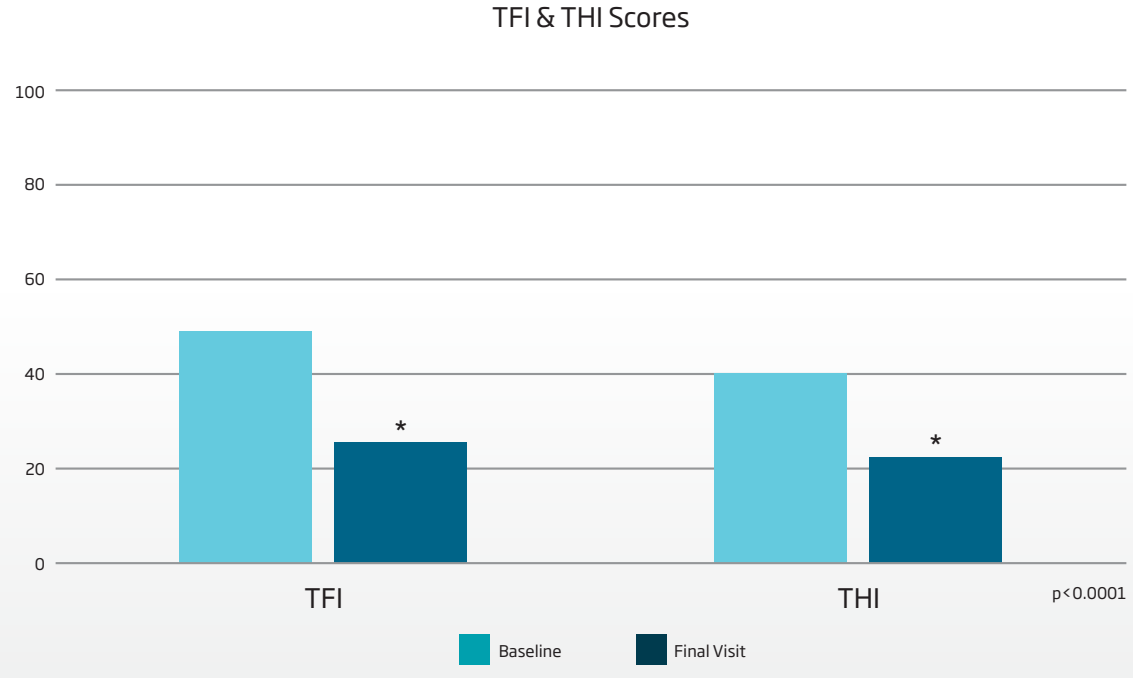

Figure 3. Median TFI and THI scores for all participants collected at the baseline (light blue) and follow-up (dark blue) appointments. Note scores for both the TFI and THI had a statistically significant ($p < 0.0001$) reduction from baseline to the end of the treatment period at 12 weeks.

Summary

The "one size fits all" mentality cannot be applied to patients undergoing tinnitus management therapy. Clinicians should be aware of the available tools and resources when initiating intervention plans and tailor them according to the unique needs of each individual. As demonstrated by the partner study with Sanders and colleagues (2023), new and experienced hearing aid users experienced benefit from Oticon hearing aids equipped with Tinnitus SoundSupport™. Appreciating the nuances of sound therapy technology coupled with a customized approach to counseling–including making appropriate referrals as necessary–is critical to optimize patient outcomes.

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