Hearing Aid Users Received Additional Benefit in Their Tinnitus Journey with Lenire® Bimodal Neuromodulation Treatment

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Tinnitus, commonly known as ringing in the ears, is the phantom auditory sensation that affects 10–15% of the adult population[1-4]. Tinnitus is a symptom of various conditions.

Hearing loss is the leading cause of tinnitus[5,6] and fitting hearing aids is one of the most commonly used management tools. It is accepted among hearing care professionals that hearing aids can be clinically effective for some tinnitus patients or offer partial relief from tinnitus for many patients[7]. However, it's also accepted that a significant proportion of the tinnitus patient population with hearing loss may not experience benefit for their tinnitus from hearing aids[8].

Treatment pathways should consider the degree of hearing loss, the patient's primary health concern (hearing loss or tinnitus), and other related comorbidities.

When a patient presents with both hearing loss and tinnitus, hearing aids are often provided in conjunction with other therapies. These include, but are not limited to:

- Cognitive Behavioral Therapy (CBT)[9]
- Tinnitus Retraining Therapy (TRT)[9]
- Non-invasive Neuromodulation[10,11]

This article will examine the real-world outcomes of 214 patients with bothersome tinnitus treated with **Lenire®** at the Alaska Hearing & Tinnitus Center. Eighty-eight patients were already hearing aid users prior to seeking treatment with Lenire, and 126 were non-hearing aid users (Figure 2a).

Bothersome tinnitus was defined in patients by scoring 38 or greater on the Tinnitus Handicap Inventory (THI) at the initial assessment.

What is Lenire?

Figure 1. Lenire® tinnitus treatment device.

Lenire (Figure 1) is the first and only FDA-approved bimodal tinnitus treatment device. Lenire's combination of proprietary audio and mild tongue stimulation is clinically proven[12-14] to provide relief from bothersome tinnitus. Lenire has been available in the United States of America since the device was granted De Novo FDA Approval in March, 2023.
Lenire consists of three components:

- **Lenire Controller**: Connects to the wireless headphones and Lenire Tonguetip®. The Lenire Controller allows users to adjust the tongue stimulation and audio volume.
- **Lenire Tonguetip**: Delivers mild pulses to the surface of the tongue.
- **Wireless Headphones**: Plays proprietary audio that pairs with tongue stimulation.

Alaska Hearing & Tinnitus Center Real-World Review Results

All 214 patients were fitted with the device by a Lenire-trained audiologist if they met the Alaska Hearing & Tinnitus Center standard of care eligibility criteria at the initial assessment.

Patients were recommended to use the device for two 30-minute sessions daily, which could be back-to-back. Patients with hearing aids were advised to take out their hearing aids during treatment. At the initial assessment, all patients were asked if they had used hearing aids within the last 90 days; their responses are shown in Figure 2a.

A review appointment occurred 10–14 weeks after device fitting. During this appointment, patients were asked “Do you find Lenire beneficial to your tinnitus journey?” to which they answered “Yes” or “No”.

As seen in the general tinnitus population, there is a lower number of females than males seeking treatment for their tinnitus (Figure 2b). In line with the demographic of patients beginning their hearing care journey, the majority of patients were between 50 and 70 years of age (Figure 2c).

As a population ages, the number of hearing aid users increases. These results align with published data, which show that the average age of hearing aid owners in the United States is 66 years[15].

Figure 2. a. Percentage of patients with hearing aids and without hearing aids. b. Gender by hearing aid use. c. Hearing aid status by age.

Of the 214 patients who returned for assessment, 92% of hearing aid users (Figure 3a) and 86% of non-hearing aid users (Figure 3b) reported that they found Lenire to be beneficial.

This high “Yes” response rate was observed in both groups, irrespective of whether a patient was currently using hearing aids.

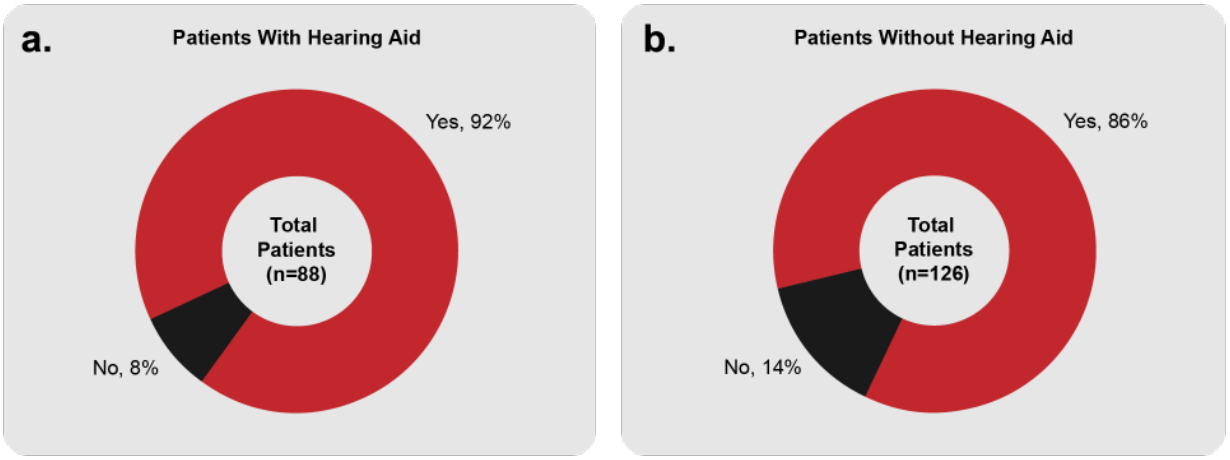

Figure 3. Response to “Do you find Lenire beneficial to your tinnitus journey?” at the 10–14 weeks assessment among a. patients with hearing aids and b. patients without hearing aids.

Where Does Lenire Fit in the Tinnitus Care Lifecycle?

Results from the Alaska Hearing & Tinnitus Center suggest that the use of a hearing aid does not impact the treatment efficacy of Lenire.

These results highlight that patients with hearing aids seek additional tinnitus treatment and that patients with hearing aids gain additional benefits from treating tinnitus with Lenire. As a result, recommending Lenire at the start of a tinnitus care journey may be more beneficial for patients whose primary complaint, or reason for visiting, is related to tinnitus.

- Lenire may be more economical for patients who want to treat their tinnitus but are not seeking hearing aids and want to save on purchasing both devices in a short period of time.
- Lenire can provide additional relief to those patients who may have received some tinnitus relief from hearing aids but are still seeking further improvement.
- Lenire can provide a clinically meaningful benefit to patients with hearing aids who may not have benefited from managing their tinnitus with hearing aids.

Evidence from this real-world data demonstrates how bimodal treatment can be integrated into a patient’s hearing health journey, regardless of their current stage. It also shows that this approach can further alleviate tinnitus beyond the relief provided by hearing aids alone.

As the device is provided by more and more clinics across the United States, the collection and analysis of further real-world data will better inform the optimal tinnitus treatment pathways across different patient populations.

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