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Assessing the efficacy of a novel bone conduction tinnitus suppression device: a 30-day pilot study on clinical and audiological outcomes

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Abstract

Purpose This pilot study investigated the efficacy of a novel Tinnitus Retraining Therapy (TRT) device utilizing bone conduction white noise generation, in treating tinnitus in a normal hearing population.

Methods This study was designed as a prospective, single-arm, observational trial in an outpatient clinic at a tertiary referral center, with 30 consecutive normal hearing patients with tinnitus. Tinnitus-specific questionnaires, namely the Tinnitus Handicap Inventory (THI) and Tinnitus Functional Index (TFI), translated and adapted to European Portuguese were administered. Patients were categorized into Group A (tinnitus characteristics within the device's maximum output performance) and Group B (outside the device's maximum output performance).

Results 69% of the participants showed improvement in their TFI scores, with Group A exhibiting a significant mean reduction of 10 points ($p = 0.0004$). The device was well-tolerated, with no adverse effects reported.

Conclusion The novel bone conduction tinnitus suppression device showed promise in reducing the impact of tinnitus, particularly in patients whose tinnitus profile is within the device maximum performance output. This improvement in TFI scores in the majority of the participants, observed after just a 30-day period, highlights the potential of specifically tailored sound therapy delivered via bone conduction in tinnitus management.

Keywords Tinnitus · TRT · Bone conduction sound generator · TFI · THI

Introduction

Subjective tinnitus refers to the perception of sound that arises solely from neural activity within the nervous system, without any corresponding mechanical or vibratory activity in the cochlea and independent of external auditory stimuli [6]. Prevalence rates suggest that it affects approximately 12 to 30% of adults [12]. The neurophysiological model of tinnitus highlights the emotional processing as a pivotal factor in the onset of tinnitus-related distress, proposing habituation as a key strategy for alleviating such distress [8].

Currently, sound therapy is recognized as a treatment option in the American Academy of Otolaryngology (AAO) guidelines; however, a definitive standard for treating tinnitus in patients with normal hearing has not been established [17]. Tinnitus habituation, defined has the reduction of both perception and reaction of tinnitus, can be facilitated through Tinnitus Retraining Therapy (TRT) [8, 15]. TRT primarily relies on counseling, education, and sound therapy [7]. For patients with hearing loss, hearing aids may be employed, ensuring continuous auditory stimulation throughout the day. This study examines the efficacy of a novel wearable sound generator, the Tinearity™ G1, in a normal-hearing population with tinnitus. This device, affixed to the skin behind the ear, converts white noise into vibrations, which are then transmitted through the skull to the inner ear via bone conduction. As a bone conduction device, it can provide a more natural sound quality and avoids the occlusion effect commonly associated with air conduction devices [4]. Additionally, the use of bone conduction reduces discomfort by keeping the ear canals open, differing from the currently available sound therapy devices that can be worn as in the ear or behind the ear devices, with an output of white noise, sound focused to the frequency band of the patient's tinnitus or music. The Tinnearity device

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performance has a frequency range from 800 Hz to 10 kHz with a maximum output of 48dB HL at 2–4 kHz (Fig. 1).

Despite the availability of psychoacoustic tinnitus measurements [2], the absence of biomarkers or objective measures for tinnitus necessitates the use of specific questionnaires to evaluate its severity. The Tinnitus Handicap Inventory (THI) [14] and Tinnitus Functional Index (TFI) [13] are two of the most widely utilized instruments for this purpose. Both the aforementioned tools are self-report questionnaire measuring severity and negative impacts of tinnitus. THI has 25 questions, covering three domains, functional (limitations caused by tinnitus), emotional (affective responses to tinnitus) and catastrophic (probes the most severe reactions to tinnitus, such as loss of control, inability to escape from tinnitus, and fear of having a terrible disease). TFI addresses 8 domains of negative tinnitus impact: Intrusive (unpleasantness, intrusiveness, persistence), Sense of Control (Sc), Cognitive (C), Sleep disturbance (SL), Auditory (A, auditory difficulties attributed to tinnitus), Relaxation (R), Quality of life (QOL) and Emotions (E). A THI score of 0–16 means "no or slight handicap", 18 to 36 indicates "mild", 38 to 56 indicates "moderate", 58 to 76 indicates "severe", and a score of 78–100 is classified as "catastrophic handicap". Concerning TFI, scores between 0 and 18 are low severity, between 18 and 42 are lower moderate, scores between 42 and 65 are upper moderate and scores greater than 65 are high severity.

The aim of this study is to assess the effectiveness of the Tinearity™ G1, a novel device, in a 30-day pilot trial conducted on individuals with normal hearing. Sound therapy for tinnitus traditionally relies on air conduction. However, this study investigates an alternative approach using bone conduction. This pathway may offer unique benefits, potentially resulting in improved outcomes for individuals with tinnitus.

Methods

This study was designed as a prospective, single-arm, observational trial, involving 30 consecutive normal (<30 dB HL PTA) hearing patients with tinnitus, recruited from an outpatient clinic at a tertiary hospital in Lisbon. Participants were instructed to use the Tinearity™ G1 device for a period of 30 days. The trial was conducted from July 1st to September 30th, 2023. The study protocol was submitted and approved by the Ethics Committee of the Lisbon Medical Academic Centre, report n264 (CAML).

Tinearity™ G1 comprises three components: (1) the sound generator, (2) an adapter and (3) a charger. The sound generator is attached to the skin behind the ear by means of the adapter, it has an on/off switch and two buttons to regulate sound intensity. The sound generator is designed to generate white noise to provide relief and to treat patients suffering from tinnitus. The adapter is a disposable device that serves as a mechanical connector between the sound generator and the user. The adapter is made up of a plastic holder that is compatible with the sound generator and a

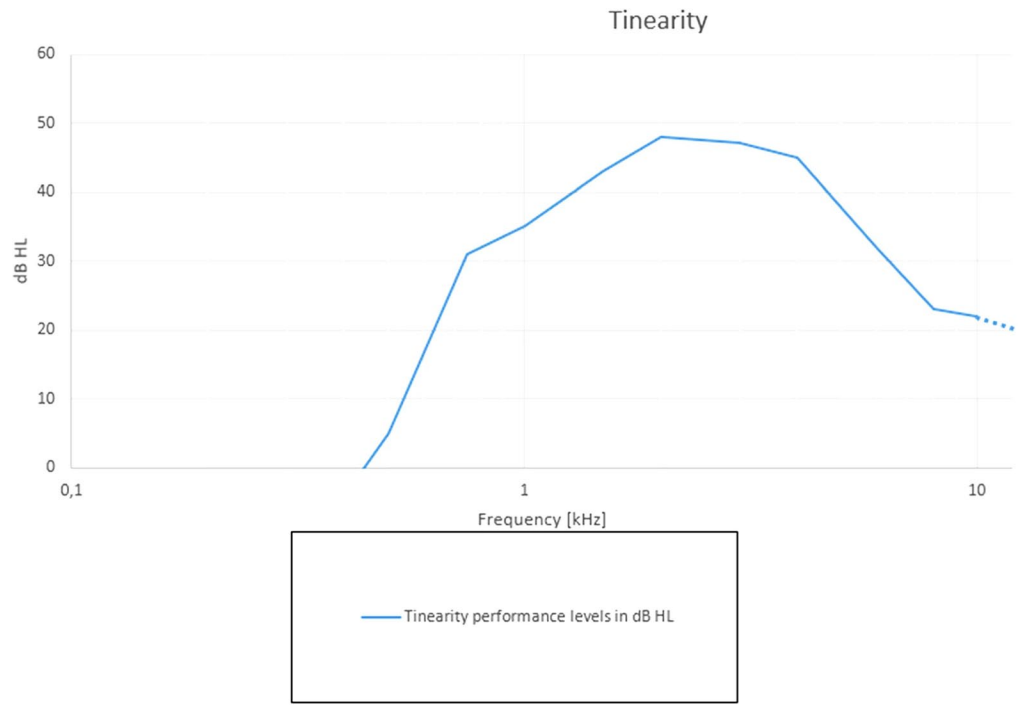

Fig. 1 Tinearity maximum output diagram in dB HL

suitable tape to be attached to the user's skin behind the ear (supplemental Figs. 1 and 2). The adapter is a single use device and is designed to be removed daily after each treatment. The sound generator uses a re-chargeable battery as a power source. Although bone conduction can theoretically deliver equal sound to both inner ears, we opted for bilateral placement. Nevertheless, a single Tinearity device, rather than bilateral placement, might provide similar therapeutic benefits. This approach may simplify treatment, reduce costs, and improve accessibility for patients.

Inclusion criteria for the study were: presence of tinnitus, regardless of type or duration, age over 18 years, non-pregnant status, a pure tone average (PTA) of 30 dB HL or less in both ears, bilateral type A tympanogram (Jerger classification), no known otologic or neurologic disorders, and no history of anti-depressive, anti-epileptic, or anti-anxiety medication use for tinnitus treatment.

Collected demographic data included age, sex and education level. Tinnitus characterization included duration [classified as either long term (>6 months) or short term (<6 months)], laterality (uni or bilateral), and whether it was pulsatile or not and intermittent or continuous.

Participants were asked to rate the impact of the tinnitus on their quality of life (QoL) on a scale from 0 (no impact) to 10 (massive impact). Tinnitus-specific questionnaires, namely the Tinnitus Handicap Inventory (THI) and Tinnitus Functional Index (TFI), translated and adapted to European Portuguese were administered.

At baseline (day 0) all patients underwent pure tone audiometry, tympanometry, tinnitus matching (for pitch and loudness), and uncomfortable level (UCL) measurement. Patients were divided into two groups based on the pitch and intensity of their tinnitus. Group A included those whose tinnitus frequency (800 Hz to 10 kHz) and intensity (up to 48 dB HL at 2–4 kHz) matched the range of sounds produced by the device. Patients whose tinnitus did not match this range were placed in Group B. The rational being that group A patients can obtain an ideal mixing point where they are able to hear both their tinnitus and the white noise at equal intensity.

On day 0, each participant underwent a 10-minute suppression test using the Tinearity™ G1, set at a volume exceeding their tinnitus level, if possible. For this test, the device is set so the sound generated by the device completely surpasses the patient's tinnitus, thus suppressing the perception of tinnitus for the established period. Post-test, they rated the device's efficacy in tinnitus suppression on a scale 1 (irrelevant) to 5 (very good). Following this, patients received counseling based on the Jastreboff tinnitus neurophysiologic model [6]. They were instructed on device placement on both mastoids using skin tape and a plastic adaptor, regardless of whether their tinnitus was unilateral or bilateral. Patients were also guided on adjusting the volume to achieve a mixing point where both their tinnitus and the generated white noise could be heard at equal intensity. They were instructed to use the device continuously for 8 h daily (either during the day or at night) for 30 days. Consent for participation was obtained at this stage.

During the first week of the trial, daily phone calls were made to monitor adherence, handle device-related issues, and check for adverse effects. This was followed by weekly calls. On day 30, participants returned for repeat audiometric evaluations, and questionnaire assessments.

Data from days 0 and 30 were anonymized and analyzed using StatXact version 11.1.0. Isolated changes in tinnitus loudness (for each ear) and THI scores were statistically evaluated using a 2-sided Wilcoxon signed rank test [16] with significance set at p-value<0.05. The TFI scores (total and subgroup) between the two subgroups were compared using a 2-sided Wilcoxon rank sum test [16], with statistical significance also set at a p-value<0.05.

Results

The study initially included 33 patients. However, 3 patients opted out after the suppression test on day 0 and one on day 30. Despite still perceiving tinnitus, the later ultimately chose not to participate in the questionnaire assessments due to the challenges in accurately determining the loudness and pitch of their tinnitus. The statistical analysis of the TFI did not include one patient because he provided only 18 valid answers in the baseline evaluation of the TFI. The participant group had a median (±Std) age of 57±11.5 years, 62% females. Educational backgrounds were diverse: 28% with elementary education, 17% with secondary school education, and 31% holding a bachelor's degree, 21% with a master's degree, and 3% with a PhD.

Audiometric evaluation revealed a mean (±Std) PTA of 15.40±8.45 dB HL for the right ear and 15.14±10.64 for the left ear. All participants had a type A tympanometry. The UCL was 86.3±17.3 (median±standard deviation) dB HL above the PTA.

Tinnitus characteristics showed that 86% of the patients had experienced tinnitus for longer than 6 months. The condition was bilateral in 59% of cases and 86% reported non-pulsatile tinnitus. The mean (±Std) QoL impact was rated at 6.62±2.69.

The average tinnitus loudness-match was 30 dB (±20.21, ranging from 10 dB to 90 dB) and the average pitch-match was 8 kHz (ranging from 125 Hz to 12000 Hz). Baseline THI and TFI were 40.83±18.98 and 51.80±24.22, respectively.

55% of patients fell within the G1 device's scope (Group A). Suppression test results indicated an average response

Table 1 THI at baseline and after the 30-day trial

THI				
Group	Statistica	Baseline	1 Month	1 Month–Baseline
All	Min	12	4	-20
	Median	40.00	32.00	-4.00
	Max	78	88	26
	Mean	40.83	37.72	-3.10
	Std	18.98	22.04	11.77
	P-value	NA	NA	0.0735
Within G1 scope	Min	12	4	-20
	Median	43.00	32.00	-7.00
	Max	78	84	26
	Mean	41.63	36.75	-4.88
	Std	21.14	23.35	11.62
	P-value	NA	NA	0.0815
Not within G1 scope	Min	20	8	-16
	Median	40.00	38.00	-4.00
	Max	66	88	24
	Mean	39.85	38.92	-0.92
	Std	16.72	21.21	12.04
	P-value	NA	NA	0.4097
P-value		0.9053	0.7869	0.4276

[z,2] Wilcoxon signed rank test. 2-sidd

[y,3] Wilcoxon signed rank test. 2-sidd

[x,4] Wilcoxon signed rank test. 2-sidd

[w,5] Wilcoxon rank sum test. 2-sided

Table 2 TFI at baseline and after the 30-day trial

Group	Statistica	Baseline	1 Month	1 Month– Baseline
All	Min	10.42	4.40	-26.40
	Median	51.80	43.60	-5.20
	Max	93.33	97.92	27.77
	Mean	48.51	43.15	-4.64
	Std	24.22	25.63	12.38
	P-value[z,2]	NA	NA	0.0322
Group A	Min	11.60	4.40	-26.40
	Median	50.40	38.60	-8.80
	Max	93.33	97.92	4.58
	Mean	50.22	39.52	-9.61
	Std	27.10	26.08	8.66
	P-value[y,3]	NA	NA	0.0004
Group B	Min	10.42	14.40	-20.17
	Median	54.17	43.60	0.80
	Max	72.80	92.17	27.77
	Mean	46.54	47.63	1.09
	Std	21.32	25.36	13.81
	P-value[x,4]	NA	NA	0.9460

[z,2] Wilcoxon signed rank test. 2-sidd

[y,3] Wilcoxon signed rank test. 2-sidd

[x,4] Wilcoxon signed rank test. 2-sidd

of 3.68 ± 1.25 among the 29 included patients (Group A 4.12 ± 1,0; Group B 3.23 ± 1.24).

After 1 month, there were no significant changes in PTA, tinnitus pitch or intensity (supplemental Tables 1 and 2) as well as in THI scores ($p = 0.073$) (Table 1).

A significant reduction was observed in the mean TFI scores across the population, from 48.5 to 43.2 ($p = 0.0322$), with 69% of subjects showing improvement. This overall improvement was primarily attributed to group A (within G1 scope), having a mean reduction of 9.6 points ($p = 0.0004$) whilst group B didn't change their score (average increase of 0.8, $p = 0.9460$) (Table 2).

Throughout the follow-up period, no adverse effects were reported. The most common issue was the need to frequently replace the tape of the device's plastic holder, a necessity attributed to the heat experienced during the study period in Portugal. Three patients required a replacement of one of the devices due to technical malfunction.

Discussion

This pilot study was conducted over a brief time period, capitalizing on the frequent occurrence of tinnitus, particularly among normal hearing patients [11], which is a common reason for referral to our ENT center. This scenario enabled the recruitment of 30 consecutive patients with diverse educational backgrounds and a broad range of tinnitus characteristics. The tinnitus impact of quality of life in this group was notably high, averaging 6.62 out of 10. Given the lack of consensus on effective treatment modalities for tinnitus treatment in normal hearing patients, coupled with its prevalence and significant impact on quality of life, it is imperative to explore viable solutions for this patient population.

At the outset of the study, the median scores for the THI (40) and the TFI (52) indicated a moderate severity of tinnitus [13, 14] in our population. While not the primary focus of our study, we observed that the device was capable of tinnitus suppression in most cases, with an overall average response of 3.6 (1 = irrelevant, 2 = insufficient, 3 = sufficient, 4 = good, 5 = very good). Group A, whose tinnitus fell within the scope of the device's generated white noise, demonstrated better suppression test outcomes. It is, therefore, crucial for patients to be educated on correctly programming the white noise near and below the true mixing point, where both the tinnitus and the generated sound are audible. This approach is key to habituation, one cannot learn to tolerate a sensation that is not perceived [18].

Both THI and TFI are widely utilized in tinnitus assessment, with the latter being considered more sensitive to treatment-related changes [5]. The three-domain format of the THI with three susbscales is not as sensitive to change as

the TFI [13], which can justify the absence of change in THI levels for both groups in a 1-month trial, as TFI can capture smaller, more gradual improvements in tinnitus-related distress, particularly in areas like cognitive interference or sense of control, which might not be reflected in the THI's more emotionally-focused domains.

Concerning TFI, the clinically relevant minimum difference remains a topic of debate [10, 19]. In our study, 69% of patients showed improvement in their TFI scores, predominantly in group A. This suggests that the frequency and intensity output of the device are critical for achieving effective mixing points and, therefore, positive TFI outcomes.

In Group A the mean TFI score reduction was 10 points. While this difference is statistically significant ($p=0.0004$), the clinical relevance of the change may be subject to interpretation. A TFI global score change of 13 [13], which was considered as the cutoff for clinical significance, and 22.4 points [10] were suggested to indicate a meaningful change beyond measurement error. In our study, 6 participants experienced a reduction of more than 13 points, while only 1 patient achieved a reduction of more than 22.4 points. Among the first, two patients demonstrated reductions of 20.17, 22.00 and 26.40 points, respectively (supplemental Table 3). Despite this, the significant change observed after just a 30-day pilot study is promising, warranting further investigation in longer-term studies [11]. Two previous studies [3, 9] showed an average improvement of 13,5 TFI points at 3 months and 20 THI points at 6 months, respectively, using air conduction sound therapy. However, these devices often face limitations related to discomfort and occlusion, which hinder patient compliance and long-term use [3].

Group B showed a wide range of TFI outcomes, including a patient who improved by 20 points, but the group's average score did not change significantly. This finding supports the notion that optimal results are contingent upon the tinnitus pitch and intensity falling within the device's scope, which did not occur with patients on group B. The lack of response in this group over the short study duration suggests that ideal candidates for this device may be identified through intensity and pitch tinnitus matching. Moreover, a device encompassing a broader frequency range and higher intensity levels might offer therapeutic benefits to a larger patient population.

TRT has shown to improve THI and TFI scores after at least 6 months [1], but the referred study did not clarify the benefit derived solely from the sound generator in normal hearing patients. The results of our 30-day trial in 29 consecutive patients are encouraging and provide promising insights into the efficacy of the Tinearity™ G1 device in managing tinnitus in a normal hearing population. While the study shows statistically significant results, the clinical relevance is debatable due to the modest magnitude of change, the short duration of the study, the small sample size, and the variability in treatment effectiveness across different patient groups. Still, the study's findings highlight the potential of sound therapy, particularly white noise generation through bone conduction, as a viable option for tinnitus habituation. Our results seem to support the neurophysiological model of tinnitus, where a suppression process by appropriately set white noise yields positive outcomes. Also, no adverse effects were reported during the study, suggesting the safety and tolerability of the Tinearity™ G1. None of our patients dropped out of the study due to unwillingness or unease to use the device, a limitation that has been pointed out when using standard air-conduction devices and hearing aids [1]. No data log is recorded so the usage time of the device is self-reported.

Future long-term trials are needed to refine patient selection criteria, including the potential for pitch and intensity matching, and to evaluate devices with expanded frequency range and broader intensity span. Such research could greatly contribute to the field of tinnitus management, offering hope to a significant portion of the population suffering from this condition. The potential for customized sound therapy, tailored to individual tinnitus characteristics, could revolutionize the approach to tinnitus treatment, paving the way for more personalized and effective management strategies.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00405-025-09410-z.

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Declarations

Conflict of interest There are no relevant conflicts of interest. The study protocol was submitted and approved by the Ethics Committee of the Lisbon Medical Academic Centre (CAML), report n264.

References

1. Bauer CA (2017) The effect of tinnitus retraining therapy on chronic tinnitus: A controlled trial. Laryngoscope Invest Otolaryngol 2(4):166–177
2. Henry JA (2016) Measurement of tinnitus. Otolaryngol Neurotology 37(8):e276–e285
3. Henry FM (2015) Validation of a novel combination hearing aid and tinnitus therapy device. Ear Hear 36(1):42–52
4. Holgers KM, Håkansson B (2002) Sound stimulation via bone conduction for tinnitus relief: A pilot study. Int J Audiol 41(5):293–300
5. Jacquemin L (2019) Sensitivity to change and convergent validity of the tinnitus functional index (TFI) and the tinnitus

questionnaire (TQ): clinical and research perspectives. Hear Res 382:107796
6. Jastreboff PJ (1990) Phantom auditory perception (tinnitus): mechanisms of generation and perception. Neurosci Res 8:221–254
7. Jastreboff PJ (2007) Tinnitus retraining therapy. Prog Brain Res 166:415–423
8. Jastreboff PJ, Jastreboff MM (2000) Tinnitus retraining therapy (TRT) as a method for treatment of tinnitus and hyperacusis patients. J Am Acad Audiol 11(3):162–177
9. Johansen JD (2014) Effect of counseling, amplification, and fractal tones in tinnitus management. J Communication Disorders Deaf Stud Hear Aids, *2*(4), Article 1000124.
10. Fackrell K, Hall DA, Hoare DJ (2016) Psychometric properties of the Tinnitus Functional Index (TFI): Assessment in a UK research volunteer population. *Hearing Research, 220–235.*
11. Kumar M, Suresh L (2023) Effect of tinnitus retraining therapy in normal hearing individuals with subjective tinnitus: an observational study. Indian J Otolaryngol Head Neck Surg, *Suppl 1*, 596–604
12. McCormack E-JM (2016) A systematic review of the reporting of tinnitus prevalence and severity. Hear Res 337:70–79
13. Meikle M (2012) The tinnitus functional index: development of a new clinical measure for chronic, intrusive tinnitus. Ear Hear 33(2):153–176
14. Newman CW, Jacobson GP, Spitzer JB (1996) Development of the tinnitus handicap inventory. Archives Otolaryngology–Head Neck Surg 122(2):143–148
15. Rauch SD, Formby C (2019) Effect of tinnitus retraining therapy vs standard of care on tinnitus-related quality of life: A randomized clinical trial. JAMA Otolaryngology–Head Neck Surg 145(7):597–608
16. Rey DN (2011) Wilcoxon-signed-rank test. In: Lovric M (ed) International encyclopedia of statistical science. Springer
17. Tunkel DE et al (2014) Clinical practice guideline: tinnitus. Otolaryngology–Head Neck Surg 151(2 Suppl):S1–S40
18. Tyler RS, Noble W (2012) Tinnitus retraining therapy: mixing point and total masking are equally effective. Ear Hear 33(5):588–594
19. Zeman F, Koller M, Langguth B (2011) Tinnitus handicap inventory for evaluating treatment effects: which changes are clinically relevant? Otolaryngology–Head Neck Surg 145(2):282–287