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A Real-Time Sequential Phase-Shift Approach to Tinnitus Cancellation-A Pilot Study in Southern India

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Abstract

Background: Tinnitus is a common hearing disorder causing significant morbidity to a large number of people in India. There exists limited literature which demonstrates complete cancellation or mitigation of Tinnitus without loss in hearing thresholds. However, there is some data that suggests sequential phase shift approach to tinnitus cancellation. A pilot study done to validate the effectiveness of a real-time sequential phase-shift technology device in South India is presented.

Objectives: To evaluate the effectiveness of a real-time sequential Phase-Shift Approach to cancellation of Predominant Tone Tinnitus (PTT).

Methods: 13 patients aged 19-65 years suffering from chronic Tinnitus were selected from a semi-urban setting in southern India. The Tinnitus Noise Generating Tool (TNGT) identified the magnitude and frequency of PTT, after which a sequential phase shifter successfully cancelled out the monotone. After the phase cancellation was locked, patient outcomes were measured over a duration of 30 minutes.

Results: 12 out of 13 patients' Tinnitus were classified successfully using the TNGT. 7 out of the 12 patients had PTT. All 7 patients had intermittent dips or cancellations of PTT once the anti-phasic signal was implemented.

Conclusion: AReal-time sequential phase-shift solution showed promising results in our pilot study. These result show that such a device can be beneficial in managing Tinnitus in India. Further studies which identify the loss in phase synchronization along with advances in making this technology affordable and wearable are warranted.

Keywords: Tinnitus; Ringing ear; Noise Cancellation; Hearing Diseases; Hearing Loss; Bio-design Process; Affordable Medtech; Audiology; Inventing Medical Devices

Abbreviations: PTT: Predominant Tone Tinnitus; TNGT: Tinnitus Noise Generating Tool; TM: Tinnitus Masker; TRT: Tinnitus Retraining Therapy; CBT: Cognitive Behavioral Therapy

Introduction

Tinnitus is defined as the perception of an external sound in the absence of any external auditory stimulus. It commonly presents as a ringing tone in one or both the ears. Tinnitus is a common and debilitating disorder in India with a prevalence of more than 7% of the Indian population [1]. It severely affects the quality of life of around 1-3% of the world population [2]. A previous study in India was done to systematically analyse the unmet need of ineffective treatment of chronic Tinnitus in India, and a solution was proposed in response to the results [3]. Tinnitus is diagnosed using an audiology exam along with a physical examination. The majority of population afflicted with tinnitus complain modifications in behaviour such as anxiety, irritability, depression, sleep disturbances [4]. Diagnosis and evaluation of tinnitus can be carried out by audiometric tests such as pitch and loudness matching, residual inhibition, minimum masking level and loudness discomfort level that are used to understand subjective characteristics of tinnitus [5].

Current treatment predominantly involves training the patient to accustom themselves to the existing noise. Common treatment options involve Tinnitus Maskers (TM), Tinnitus Retraining Therapy (TRT) and Cognitive Behavioral Therapy (CBT) [6]. These methods have confirmed long-term benefits in management of tinnitus in chronic patients. Some treatments help in fostering habituation by conditioning the brain into not perceiving the tinnitus as an annoyance [7,8], while others attempt to mask the sound with overriding music or customized tones to suppress the annoying sound. However, most of these currently available treatment options are not able to provide significant relief in the form of complete elimination or diminishing intensity of tinnitus in real-time. They are either barely effective in masking tinnitus or are effective for long-term management, which when discontinued may result in a relapse.

Drug therapy using anti-seizure medicines like gabapentin and benzodiazepines has been unsuccessful in demonstrating significant effect in elimination of tinnitus. However, these drugs are helpful in reducing anxiety levels and have a pacifying effect [9]. Many, if not most patients with really bothersome tinnitus are found to have major depressive disorders. A study found that 118 out 100,000 people committed suicide due to the suffering being unbearable [10]. Tinnitus has been found to impact attention, working memory, and ability to complete complex tasks along with other moderate comorbidities. Predominant Tone Tinnitus (PTT) is a particular type of tinnitus defined as a single persistent frequency with varying phase and magnitude. Phase-shift mono-frequency tinnitus cancelling approaches were first suggested as early as 1985 [11]. Studies have been able to demonstrate remarkable cancellation of predominant tone tinnitus by sequentially shifting the phase of a single sinusoid upto a point where the artificially generated sinusoid is of the same frequency and magnitude as the monotone tinnitus, but out of phase by 1800 [12].

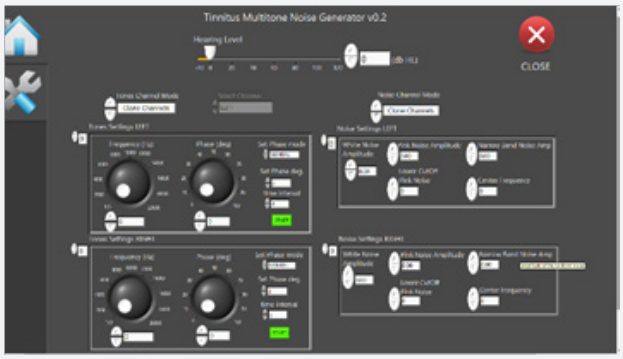

Figure 1: User Interface of the TNGT software.

However, a real-time anti-phase monotone cancelling solution is not seen in literature until now. A real-time tinnitus cancellation solution adapts to the time varying parameters of tinnitus and effectively tries to cancel out tinnitus at all times. The inherent phase of PTT is observed to vary intra-patient from time to time. It can vary every few seconds to every few days. A real-time solution based on real-time inputs from the patient will help the patient re-tune the PTT cancellation device dynamically and periodically. Such a solution requires the patient to give certain inputs regarding the frequency and magnitude of the predominant tone. Such a device is capable of helping patients achieve long-term therapeutic cancellation of PTT by re-tuning the device periodically, as and when required. We demonstrate the implementation of a real-time sequential phase-shift approach on chronic tinnitus to establish the efficacy of such a solution.

Material and Methods

I-Software Tool

A novel algorithm called the Tinnitus Noise Generating Tool (TNGT) was created in Windows on the National Instruments LabVIEWTM platform. The software is capable of generating mono-frequencies as well as multi-frequencies. If required, the software can also generate various types of noise such as pink noise, brown noise, white noise and narrowband noise. The tool first tries to identify the PTT frequency by conducting a series of tests. A single tone is played after which, the patient is asked whether the PTT frequency is higher or lower than the played tone. An algorithm is written to identify the PTT frequency in a minimum number of trials.

The amplitude of the PTT frequency is then fixed. This is again done through a series of trials with the patient. The software has a frequency resolution of 1 Hz and an amplitude resolution of 1 dB. An algorithm then sequentially shifts the phase of the sinusoid tone every 15 seconds (details explained later). The phase of the generated sinusoid at which the PTT vanishes or is minimally audible, is the phase which is anti-phasic to the PTT phase. The tinnitus noise generating tool software was initially tested to identify the amplitude and frequency of the patient's PTT and generate a sound identical and out of phase by 1800 with respect to the PTT. Figure 1 shows the outlay of the TNGT software.

II – Concept Validation

An exhaustive Clinical Immersion was done to validate whether Chronic Tinnitus is a major health concern in India. A month-long immersion consisting of a multi-disciplinary team (doctor, engineer, designer and business graduate) was conducted in the ENT department of a tertiary care hospital in southern India. The end result was an exhaustive list of more than 100 clinical unmet needs. The list was ranked based of criticality, prevalence and potential market in India. Chronic Tinnitus ranked fifth on the list, thus validating the need for a novel affordable solution.

Prior to the study, a detailed survey was conducted to understand and validate our proposed solution. 10 eminent audiologists and neurotologists were interviewed through a questionnaire to validate the process of testing of the software

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solution on patients. With this information, an inclusion-exclusion criterion was designed, elucidating the ideal patient criteria for testing this device. A protocol was devised to capture physical sound parameters of perceived tinnitus to aid generation of its equivalent artificial sound. The questionnaire is in (Table 1).

Table 1: Neurotologist and Autologist Questionnaire.

S No	List of Questions Used to Interview Neurotologists and Audiologists
1	Name
2	Date
3	Profession
4	Hospital
5	How many chronic tinnitus cases do you see in a month?
6	What proportion of these cases have predominant frequency/ single frequency tinnitus?
7	What according to you is the most effective management for chronic Tinnitus?
8	Do you think noise cancellation by phase shifting will alleviate the continuous ringing sensation?
9	Reasons if you think noise cancellation will work
10	Reasons if you think noise cancellation will not work
11	Reasons why you are not sure if noise cancellation will work or not work
12	We would like to test if noise cancellation works on patients. How would you recommend we carry out such a study?
13	Any other feedback or comments

III-Patient Selection and Characterization

Six audiology labs (sound-proof rooms) across Bangalore and one lab in Kolkata were identified as centres for carrying out the characterization. Using various artificially created tones, the TNGT is able to help the audiologist in categorizing the type of tinnitus. Patient recruitment was carried out through a series of semi-urban ENT screening camps. The semi-urban population of Bangalore was specifically targeted for this study since these areas are in dire need of affordable healthcare. The Deafness and Vertigo Clinic of Dr. Anirban Biswas was the centre for testing in Kolkata. The experiments were carried out on 18 chronic tinnitus patients (age 19-65 years) who were severely affected by the condition. The experiments were carried out over 6 months across various audiology labs.

Before the tests were carried out, the patients underwent characterization, a process by which the selected patients were classified based on the type of tinnitus they had. The characterization also assessed the patient's hearing threshold and obtained physical parameters of the tinnitus. This was done with assistance from the TNGT. The software was installed on a laptop and the testing was carried out in a soundproof room. The patient was aided with Sennheiser HD 202 headphones plugged to a laptop that had the following technical specifications - Intel i7 6600U 2.4 GHz core processor, 8GB RAM, Windows 8.1 OS.

IV -Experiment Protocol

The TNGT software was designed and tested to identify the patient's tinnitus and generate a sound identical in magnitude and frequency but 1800 out of phase. The algorithm subjectively (as per the identified type of tinnitus of the patient) identifies the frequency and magnitude in a systematic manner. The patient is subjected to a tinnitus equivalent sound ipsilaterally via headphones for at least a time period of 15 minutes during which the automatic sequential phase shifting of the generated sound takes place. The tool is manually programmed to automatically shift the phase of the generated sound by 6 degrees for every 30 seconds time period. If required, the phase change can be manually changed to less than 6 degrees. This way a full 180-degree cycle of phase shift of sound wave is achieved in 15 minutes. At the commencement of this cycle, the patients are asked to concentrate on their tinnitus and inform the tester when an elimination of tinnitus is perceived. If such a response is recorded, the phase shifting mechanism of the tool is made to stop and the generated sound is locked at that precise phase where elimination is perceived. At the same time, a stopwatch is clocked in to measure the time period of elimination based on the patient's perception. The phase at which the patient perceives a diminishing of tinnitus is essentially the generated sound anti-phase (1800) with respect to the patient's tinnitus sound wave. This locked generated sound is subjected to the patient for 30 minutes time period to measure any subsequent dips in the tinnitus. Each of these subsequent dips is also timed to gain insights on the elimination pattern.

Results

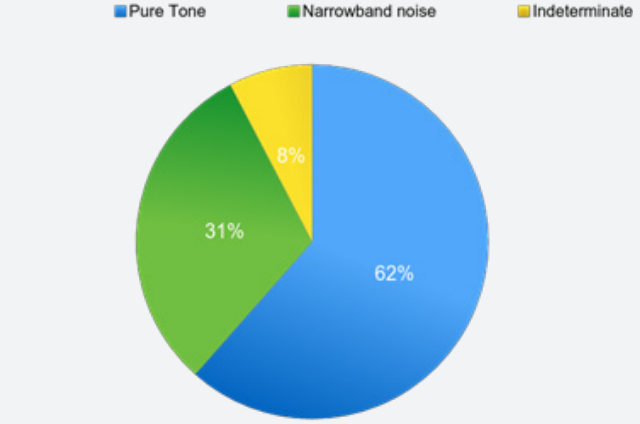

Figure 2: Patient distribution – Type of Tinnitus.

The tinnitus noise generating tool was successful in identifying the tinnitus condition of 12 out of 13 patients. The prime feature of the tool, generation of an anti-phase equivalent of perceived tinnitus resulted in real-time tinnitus elimination in chronic pure tone patients. Patients with narrowband noise tinnitus could not perceive any difference in their tinnitus condition. 1 out of the 13 patients could not identify and compare the perceived tinnitus to any sound generated by the tool and the

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patient has hence been categorized as indeterminate. shows the distribution of patients by tinnitus type, who have undergone the TNGT tests.7 out of 12 patients perceived some form of tinnitus elimination. All the 7 patients suffered from pure tone tinnitus. Multiple short bursts of dips in tinnitus were perceived when patients were subjected to phase locked tinnitus equivalent sounds generated by the tool. This means that the cancellation of the PTT was intermittent. Table 2 represents the impact of software on perceived tinnitus.

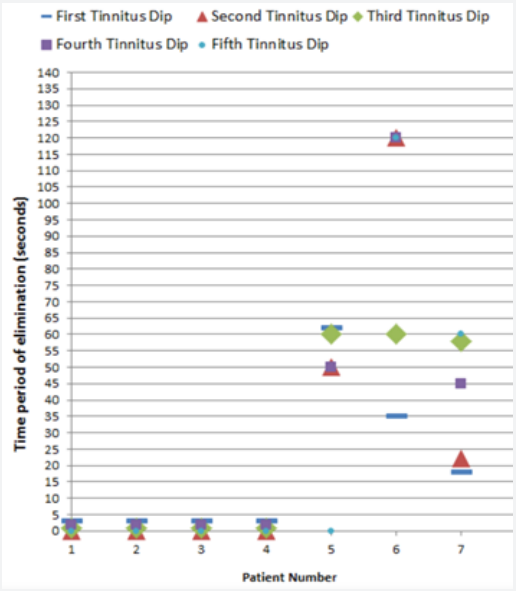

Figure 3: Duration of sequential Tinnitus cancellations (dips) per PTT patient.

Table 2: Patient Outcomes from the 30-minute test.

Tinnitus Type	Impact of the Software	No of Patients
Pure Tone	Continuous elimination for 10-120 seconds	3
Pure Tone	Continuous elimination for 1-3 seconds	4
Pure Tone	No elimination	1
Narrowband noise	No elimination	4
Indeterminate	Unable to identify and relate to the generated sound	1

3 chronic pure tone tinnitus patients perceived an elimination that lasted for a maximum time of 2 minutes. The elimination occurred 4-5 times while the patients were subjected to their respective locked phases for a fixed duration of 30 minutes. 4 pure tone patients experienced elimination for 1-3 seconds over the fixed duration. They did not perceive repeated elimination during this period. 1 among the 8 chronic pure tone tinnitus patients did not perceive any elimination during the testing. 3 out of 13 patients experienced spurts of diminishing effect of tinnitus during the time patients were subjected to the phase locked tinnitus equivalent sound. Figure 3 depicts the number of times the 7 patient's perceived elimination of tinnitus and the time period of elimination. The maximum continuous real-time elimination that was perceived by a patient was 2 minutes while the maximum total real-time elimination perceived by a patient subjected to anti-phase equivalent of the tinnitus is 7.6 minutes.

Discussion

Tinnitus can be classified based on the type of therapy chosen to manage tinnitus. Currently, Tinnitus Maskers (TM), Tinnitus Retraining Therapy (TRT) and Cognitive Behavioural Therapy (CBT) based therapies can be classified as those which try to immunize the patient towards the annoying sound. This is done by training and counselling the patient in CBT or TRT and via usage of music and specially generated tones and noise in masking devices (TM). A study by [13,14] showed that the masking therapy lead to a failure rate of 60% with only 12% experiencing a continuous relief. Tinnitus masking techniques only along with particular counselling and follow up to the hospital department then resulted in a success rate of 81%. However, this was shadowed with varying degrees of relief from patient to patient, inconsistent time of relief in the same patient giving rise to inconsistent results and doubts in the development of masking techniques that works for majority of patients [13]. Studies have shown a success rate of 70% with a year of rigorous therapy [14]. Studies by Choy et al and Lipman et al have successfully established diminishing effect of sequential phase shift treatment on tinnitus. These two studies demonstrated a success rate of 70% and 50% respectively [15,16].

These treatments are only deemed effective over long-term usage with the goal of eventual cure or temporary reduction in tinnitus intensity. There is still a major gap in the treatments that provide relief on immediate action basis. Previous studies on sequential phase shift methods to cancel tinnitus were based on a 3-4 week long treatment, where in the sequential phase shifts were performed over a period of 2-3 weeks. Each phase shift was played via an audio file over several hours in each therapeutic session. These methods are based on the approach that tinnitus is a misfiring of certain auditory neurons. A periodic playing of audio files which are sequentially phase-shifted has a neuromodulatory effect that can potentially permanently reduce the tinnitus intensity, either completely or partially [17].

Real-time classification and measurement of the type of Tinnitus along with simultaneous generation of anti-phasic monotone signals to cancel PTT was tested in this study. It resulted in a brief but immediate elimination of tinnitus in chronic pure tone tinnitus patients whereas no impact was seen in patients suffering from narrowband tinnitus. One of the main advantages of this method over other methods is that the patient does not have to go through any training or therapy over several weeks or months. The effects are almost instantaneous and can potentially be long-term. This is because pure tone tinnitus patients perceive a mono frequency sound and its sound wave can be programmed, mimicked and generated. Precise

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frequencies were not identifiable in narrowband tinnitus based on the assumption that narrowband noise wave patterns are random which does not allow the destructive interference of narrowband noise tinnitus with its equivalent generated sound at any point during the testing.

We concluded that noise-like tinnitus such as narrowband noise essentially constitutes of random, multiple frequencies in contrast to pure tone tinnitus. In case of PTT, the elimination does not last for a prolonged time and occurs in repeated bouts over a period of about 30 minutes. The elimination does not occur continuously as we hypothesize that either the frequency of tinnitus characterized was off or there are multiple frequencies constituting the sound of tinnitus which have not been anti-phase locked effectively.

Conclusion

We have demonstrated that a real-time Predominant Tone Tinnitus classification and cancellation device is capable of successfully cancelling monotone Tinnitus for up to a few minutes. Although this is not a significant therapeutic duration, it warrants further investigation for innovation in affordable devices to cancel Tinnitus in real-time. There is a need for an adaptive algorithm with patient input that is capable of re-calibrating and resetting the anti-phasic cancellation signal. A portable and affordable device can go a long way in addressing the issue of Tinnitus in India.

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