

Phase Shift Treatment for Predominant Tone Tinnitus

Ruthann I. Lipman, DO - Resident in Otolaryngology; Lake Erie College of Osteopathic Medicine - Erie, PA

Sidney P. Lipman, MD; Lake Erie College of Osteopathic Medicine - Erie, PA Kirk W. Steehler, DO; Lake Erie College of Osteopathic Medicine - Erie, PA

Introduction

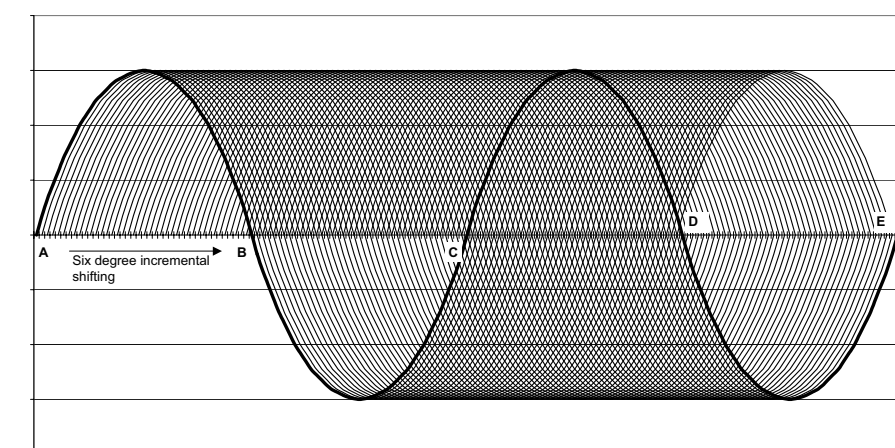
Jastreboff defined tinnitus as “the perception of a sound which results exclusively from activity within the nervous system without any corresponding mechanical, vibratory activity within the cochlea”. The American Tinnitus Association (ATA) estimates that upwards of 50 million Americans experience tinnitus to some degree with 12 million severely affected. Tinnitus imparts a substantial burden upon many patients thereby negatively impacting quality of life. It is theorized that Vincent Van Gogh may have cut off his ear during a particularly severe episode of tinnitus (associated with Meniere’s disease) in an effort to assuage the symptoms. Varied and constantly evolving speculations as to etiology and treatment of tinnitus have continued to the present day. Despite difficulties with defining and treating tinnitus, the disability that patients experience due to tinnitus is real and this continues to prompt further research into viable treatment options.

Phase shift treatment is a newly emerging technology that employs sound cancellation by utilizing the patient's unique tinnitus frequency. This is similar to the technology used in commercially available sound cancellation headphones. Predominant tone tinnitus, for the purpose of this study, is defined as tinnitus with one primary sound perceived by the patient. Predominant tone tinnitus can be represented by a sine wave depicting the individual patient's unique frequency and intensity. The difficulty lies in determining the exact timing of the peak and trough of the endogenous wave. This problem is addressed by employing progressive phase-shifting of the treatment wave (Figure 1). Initial studies by Choy indicate upwards of 84% of patients respond with a reduction in intensity of 50% or more and up to one week of residual inhibition with a notable cumulative effect of therapy.* Noik completed a study in London, UK and presented his data on 81 patients treated with this system. Of those, 70% of patients benefited from therapy.**

The purpose of this study is to independently evaluate the effectiveness of phase shift treatment for predominant tone tinnitus.

FIGURE 1

Phase Shifting of Sound Wave



Materials and Methods

This prospective, single-blind crossover study evaluates the effect of phase shift treatment on patients with predominant tone tinnitus. Subjects were recruited from August 2005 through February 2006 during their visit with an otolaryngology group in Erie, PA. 198 patients were screened for study inclusion with 40 patients being enrolled in the study. Of these, 97% (39/40) of patients completed the entire experimental month of the study. Of the subjects, 53% (21/40) were male and 47% (19/40) were female. Mean age of participants was 54 years (range 34-80 years). Mean duration of tinnitus was 11.3 years (range 3 months to 'life long'). Audiometric pure tone thresholds revealed predominantly moderate, high-frequency sensorineural hearing loss (Figure 2, 3). Mean tinnitus frequency was 7999Hz (range 600Hz-14500Hz, SD 3488Hz). The protocol was approved by the Western Institutional Review Board. Informed consent was obtained by the primary investigator.

Figure 2

Averages of Pure Tone Air Conduction Thresholds (dB HL)

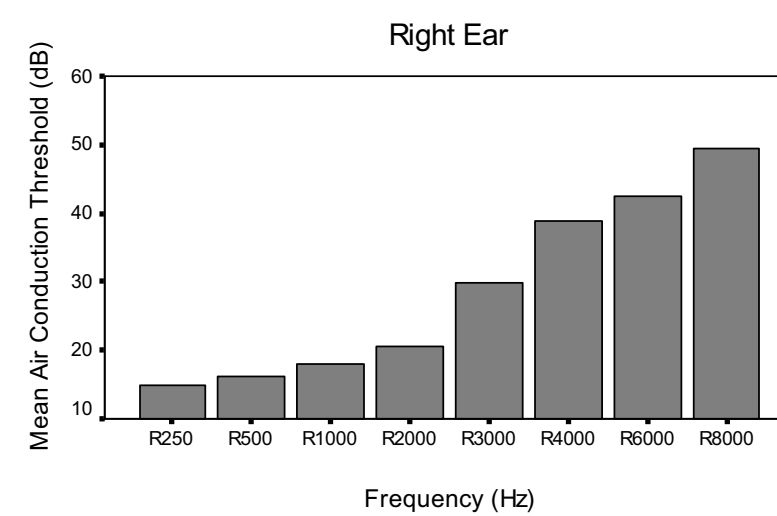
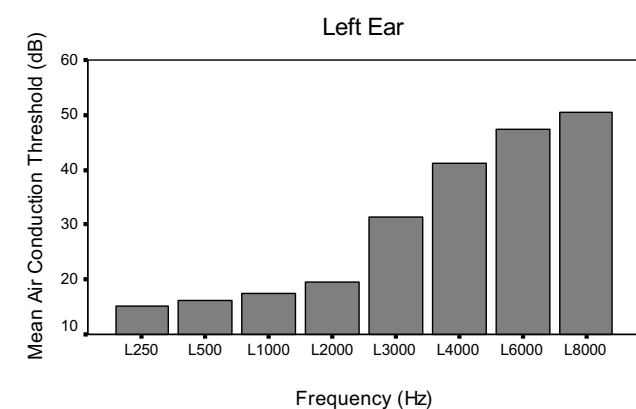


Figure 3

Averages of Pure Tone Air Conduction Thresholds (dB HL)



Inclusion and exclusion criteria are delineated in Table 1. All patients underwent complete otolaryngologic exam by one of the investigators to rule out organic causes of tinnitus and underwent further testing (MRI, carotid ultrasound) based upon clinical judgment. Comprehensive audiologic exam was performed on all participants, as well as an initial matching session with the “Phase Out” treatment device (PTD) provided by Tinnitus Control Inc. (TCI) (New York, NY). The PTD provides incremental changes in frequency from 100Hz to 13,000Hz (Table 2). Changes in intensity are in increments of 1dB with a minimum of 0dB and a maximum of 110dB.

Table 1
Inclusion and Exclusion Study Criteria

Inclusion Criteria	Exclusion Criteria
*Minimum age of 18 years	*Defect in cognition
*Tinnitus for minimum of 3 months	*Acoustic neuroma
*Predominant tone tinnitus by history	*Aortic/outflow tract stenosis
*No more than 60dB hearing loss in frequency of tinnitus	*Pulsatile tinnitus
	*Frequent ear infection
	*Pregnancy
	*Inability to correctly use test equipment

Table 2
Incremental Change in Frequency per Turn of PTD Knob

Frequency range (Hz)	Incremental change (Hz) per turn of PTD knob
100-2000	10
2000-3500	20
3500-5000	50
5000-13000	100

The experimental month of the study consisted of an initial two weeks of control during which each patient was treated three times per week. This was followed by two weeks of active treatment that was structured identically to the control weeks. Patients were blinded as to their treatment status throughout the study and could not perceive variations in sound during phase-shifting. Appointments were started with an initial frequency and intensity match to their endogenous sound, as well as a threshold determination. This was accomplished by playing a digital audio file through the headphones and asking the patient to turn a control knob on the PTD until the sound most closely matched their tinnitus. The frequency and intensity were recorded and the process was repeated a minimum of three times for each patient, with the average of these matches used as the treatment parameter for the visit. The device was then programmed and the patient listened to the digital audio file for 30 minutes. During control weeks, the sound wave was played back to the patient but was not phase shifted. During treatment weeks, the sound wave was phase shifted by the PTD 6 degrees every 30 seconds over 360 degrees (Figure 1). After each treatment was complete an additional tinnitus match and threshold measurement was obtained.

In order to maintain consistency with previous studies with this technology, treatment success was defined as a drop in tinnitus intensity of 6 or more decibels. Based upon the logarithmic nature of the decibel scale, a decrease of 6dB represents a 50% reduction in intensity. Intensity discrimination of the human ear varies depending upon the frequency of sound presented, but ranges from .5-1.5 dB.²

The Tinnitus Handicap Inventory (THI) was administered prior to every treatment and served as one of three outcome measures. A total score (range 0-100) is calculated, with lower scores indicating less degree of perceived handicap and with five handicap grades ranging from 'slight' to 'catastrophic' based on total score (Table 3).³ With an initial score of 20 or greater at baseline, self-perceived handicap scales serve as functional outcome measures when used in a pre- and post-treatment paradigm, with reduction in self-perceived handicap as the desired positive outcome.^{3,4}

Table 3
THI Grades and Total Scores

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Slight handicap	Mild handicap	Moderate handicap	Severe handicap	Catastrophic handicap
0-16	18-36	38-56	58-76	78-100

Patients were asked to keep a tinnitus diary and to evaluate their tinnitus two times a day using a Likert scale (0=no tinnitus, 1=mild tinnitus, 2=moderate tinnitus, 3=severe tinnitus).

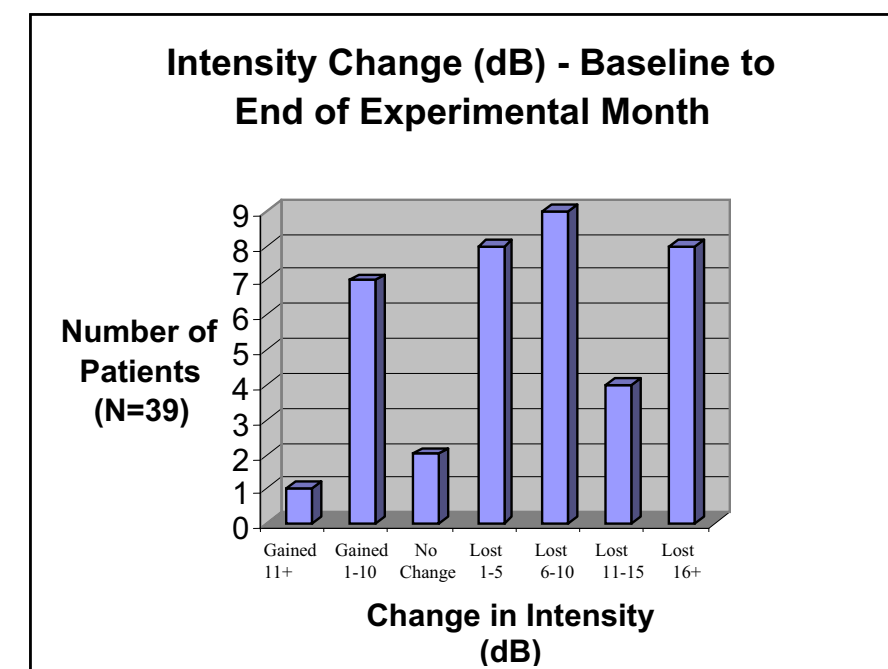
Analysis was undertaken with the SDATA and SPSS programs. Descriptive statistics were analyzed including age, gender, hearing aid use, duration of tinnitus and audiometric parameters. Change in intensity (dB) over the course of the study was evaluated, as well as Ordinary Least Squares Regression to quantify the relationship between treatment and change in intensity with control variables. The handicap inventory was evaluated including means, paired samples T-tests with correlations, 95% confidence intervals, and p-values. The tinnitus diary served as a subjective measure of tinnitus volume.

The test units, headphones and laptops were provided at no cost by TCI. TCI also provided funding for the initial IRB submission.

Results

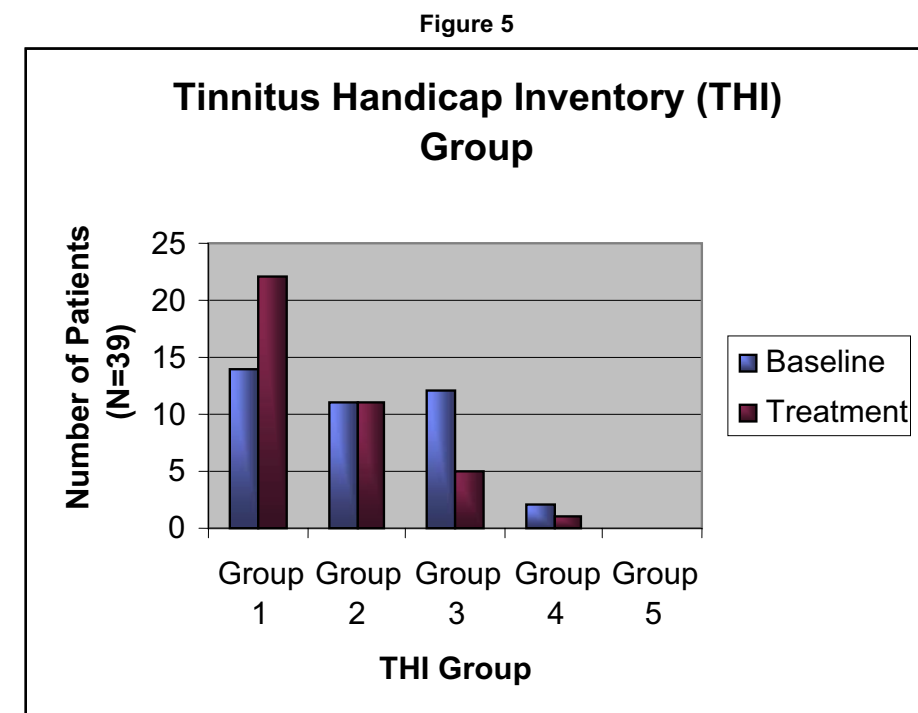
Initial intensity comparisons show a strong relationship between treatment and resultant tinnitus intensity. Mean dB reduction was 9.2dB (range: gained 39.4dB - lost 65.4dB), SD of 18.8dB, with 53% (21/39) of subjects achieving successful treatment over the experimental month of the study based upon a minimum of 6dB reduction in intensity. Quantitative intensity change compared with number of patients is depicted in Figure 4. Of those patients who showed intensity increases,

Figure 4



only one patients' intensity continued to increase with each treatment. This patient elected to stop treatment after the experimental month. He was evaluated one month later, and his intensity had decreased to baseline levels. Ordinary Least Squares Regression analysis was completed with a dummy variable for treatment indicating that the control weeks are not significant. There is a significant relationship between treatment and intensity (T = 3.5). In this model we controlled for several variables, all of which were statistically significant. It was especially important that we controlled for frequency as it was highly significant (T = 12.8). 28% of the variation in intensity is explained by this model (R-squared = .28).

Figure 5 compares THI grade between baseline and treatment. Thirty percent (12/39) showed a decrease of one THI grade, 7% (3/39) by 2 THI grades, and 2% (1/39) of patients increased by one THI grade. Utilizing patient diaries, 46% (18/39) of patients



reported periods of complete residual inhibition (no tinnitus) ranging from 1 hour to 7 days after treatment (average 2 days). No patients reported complete residual inhibition during control weeks.

Discussion

A number of treatments employ sound for therapeutic effect including TRT, masking, the Ultra Quiet system, and sequential sound therapy.^{5, 6, 7, 8, 9} Treatment in this study also employs sound, but in a novel way. These therapies are all non-surgical, non-pharmacologic and have shown positive response to treatment. Many of these treatments require the user to wear a device on the ear for extended periods throughout the day which may lead some patients to discontinue use for cosmetic reasons. Studies continue to employ varying definitions of treatment success and patient satisfaction. In order to more easily compare studies in the future, standardization of objective audiologic evaluation and questionnaires is needed.

While a prospective randomized placebo controlled study would have provided the ideal conditions to prove the validity of this treatment, tinnitus as a medical entity does not lend itself well to such a study design. It is difficult, if not impossible, to non-invasively prove that a patient is experiencing tinnitus and to what degree. As such, it is conversely difficult to prove its adequate treatment. Patient generated frequency and intensity determinations during audiologic evaluation provided objective assessment, while the results of THI and patient diaries provided subjective assessment.

Duration of the experimental arm of this study may have had an effect on success rates. At the conclusion of the experimental month, patients had only received two weeks of active treatment (6 treatments total). Because benefit may be progressive and additive over time, patients who finished the experimental month may show more benefit after a longer course of therapy. Long-term studies will delineate this effect more clearly, and are merited for this reason.

Because this study was undertaken prior to the PTD's being commercially available, we were limited to the use of only two devices for the entirety, and were unable to send patients home with the devices. Long travel times to appointments and scheduling difficulties may have impacted our results. Continued therapy with more convenient availability of the device might alter outcomes. After the experimental month, a few patients clearly were responding to but elected to wait until they could purchase the device for home use before continuing with treatment.

Our study is an independent evaluation of a novel treatment in the on-going search for residual inhibition of tinnitus. Phase shift treatment may become the “Meniett Device” for tinnitus—a turnkey, user-friendly, take-home treatment for this difficult disorder. We have not been able to duplicate the 70-80% success rates of Choy and Noik, but 50-60% is good, and certainly much better than what is available to patients in a general ENT practice. Numerous physicians have tried and abandoned the use of TRT and masking because they require a large amount of resources, extensive rehabilitation and counseling. Our data demonstrates a significant decrease in tinnitus intensity after short term treatment with 46% of our patients demonstrating complete residual inhibition for 1 to 7 days.

These outcomes suggest that this device may be a valuable tool. We must remember that many of these patients have failed other therapies, or have few options for treatment available in their geographic area. Our modest success with prototype, first generation equipment may herald better results in the future.

In this era of managed care medicine, solutions for tinnitus are not uniformly covered in a comprehensive manner, leaving much of the burden of cost to the patient. Therefore, a treatment that is largely self-directed, portable, and available for home use becomes very desirable from a medical-economic standpoint. After physician determination of patient response during a designated time period, chosen responders would likely benefit from continued home use of this device.

Conclusion

Phase shift therapy for predominant tone tinnitus is moderately successful at decreasing tinnitus intensity after short term therapy. Long periods of therapy at patient determined intervals may produce even better outcomes.

References

- Jastreboff PJ. Tinnitus as a phantom perception: theories and clinical implications. In: Vernon J, Moller AR editors. *Mechanisms of Tinnitus*. Boston: Allyn & Bacon Publishers; 1995: p 73-94.
- Humes LE Psychoacoustic foundations of tinnitus. In: Katz eds. *Handbook of Clinical Audiology*. Baltimore: Williams & Wilkins Publishers; 1985: p 94-115.
- Newman CW, Jacobson GP, Spitzer JB. Development of the Tinnitus Handicap Inventory. *Arch Otolaryngol Head Neck Surg* 1996; 122: 143-148.
- Newman CW, Sandridge SA, Jacobson GP. Psychometric Adequacy of the Tinnitus Handicap Inventory (THI) for Evaluating Treatment Outcome. *J Am Acad Audiol* 1998; 9: 153-160.
- Vernon JA, Meikle MB. Masking devices and alprazolam treatment for tinnitus. *Otolaryngol Clin North Am* 2003; 36: 307-320.
- Goldstein BA, Lenhardt ML, Shulman A *et al*. Tinnitus improvement with ultra high frequency vibration therapy. *Int Tinnitus J* 2005; 11(1): 14-22.
- Lopez-Gonzalez MA, Lopez-Fernandez R. Sequential Sound Therapy in Tinnitus. *Int Tinnitus J* 2004; 10(2): 150-155.
- Jastreboff PJ, Jastreboff MM. Tinnitus Retraining Therapy (TRT) as a method for treatment of tinnitus and hyperacusis patients. *J Am Acad Audiol* 2000; 11(3): 162-177.
- Henry JA, Schechter MA, Nagler SM *et al*. Comparison of tinnitus masking and tinnitus retraining therapy. *J Am Acad Audiol* 2002; 13(10): 559-581.