ORIGINAL PAPER DOI: 10.5935/0946-5448.20180023

InternationalTinnitusJournal.2018;22(2):133-142.

Tinnitus Relief Using High-Frequency Sound *via* the HyperSound Audio System

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Abstract

Purpose: Many tinnitus patients report a reduction in their tinnitus with use of sound therapy. We were interested in determining the magnitude of tinnitus relief that results from exposure to a novel, high-frequency directional audio system.

Method: Twenty-three individuals with sensorineural tinnitus were exposed to a 30 minute sound of their choice using the HyperSound audio system. Ratings of tinnitus loudness and annoyance were measured prior, during, and after the sound exposure. Magnitude estimates of loudness and annoyance were obtained over this period. The Tinnitus Primary Functions Questionnaire was administered pre- and post-exposure to determine the degree of change in the functional impact of tinnitus. Following the exposure, the change in tinnitus loudness was quantified numerically in 1-minute intervals, and acceptability of the masker was rated.

Results: Results revealed a reduction in tinnitus loudness for 16 of 23 participants and in annoyance for 14 of 23 participants. There were three individuals who reported an increase in their tinnitus after exposure to the sound stimulus and, therefore, did not benefit from the sound therapy. A significant improvement was found in concentration abilities and in the functional impact of tinnitus with use of this sound therapy device, which was represented by an improvement in mean scores for the concentration subscale and total score on the Tinnitus Primary Functions Questionnaire. Further, for 30% of the group, a post-masking effect was observed after exposure or a reduction in tinnitus loudness after the cessation of the stimuli. Finally, 72% of the participants reported that the sound therapy was acceptable in masking their tinnitus.

Conclusion: These results indicate that the HyperSound audio system using high-frequency stimuli may be helpful in alleviating tinnitus for tinnitus sufferers. More research is needed to determine the effectiveness of the HyperSound audio system compared to clinical treatments for tinnitus.

Keywords: tinnitus, sound therapy, tinnitus treatment.

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Paper submitted to the ITJ-EM (Editorial Manager System) on August 09, 2018; and accepted on August 20, 2018.

INTRODUCTION

Chronic tinnitus produces numerous negative effects on one's lifestyle, including sleeping, emotional disturbances, concentration difficulties such as attention problems on a given task, and problems hearing conversational speech and other sounds[1-5]. Of the many tinnitus management approaches, sound therapy, or use of sound to change the perception of tinnitus or lessen its prominence, has been used effectively for decades[6-8]. More recent studies have evaluated the various sound therapy options available including wearable generators, hearing aids, and combination hearing aids and sound generators[9,10], and evidenced-based guidelines for their clinical utility are now available to clinicians[11].

Two levels of sound therapy have been explored to provide relief; (1) total masking where the tinnitus is no longer audible in the presence of the masking noise, and (2) partial masking where both the tinnitus and masking sounds are audible. Further, the mixing point has been studied, or the level below the point of total masking where tinnitus is still perceived, but blended with the masker[12]. Tyler et al.[13] conducted a controlled study of 48 tinnitus patients by comparing mixing-point masking to total masking using self-report on the widely used Tinnitus Handicap Questionnaire (THQ)[14]. Because no significant difference emerged between the two masking levels, their results indicated that both approaches to masking were equally effective in providing tinnitus relief[15].

Traditionally, sound therapy has been thought to help tinnitus sufferers by changing or suppressing one's perception (e.g., loudness) of their tinnitus, and by changing one's reactions (e.g., depression, anxiety) to their tinnitus. Studies have reported that sound therapy produces a momentary relief from the stress or anxiety caused by the tinnitus and also a distraction from the tinnitus by directing the individual's attention from the internal noise[15,16]. Further, when a masking sound is presented in the background, the loudness and annoyance of one's tinnitus may lessen, changing the perception of the tinnitus. Some tinnitus sufferers report partial or total suppression of their tinnitus following exposure to a high-level masking sound, termed residual inhibition or post-masking[17,18]. In fact, an early study by Tyler et al.[17], found that residual inhibition occurred with most patients when the appropriate sound for reducing tinnitus was selected. Further, a more recent study found that patient-specific, amplitude-modulated tones are more likely to be considered effective maskers in reducing the loudness of tinnitus compared to broadband noise[19]. Overall, the nature of acoustic stimulus implemented in sound therapy differs widely and can include environmental or musical sounds, static and dynamic sounds, and amplified sound from hearing aids. Indeed, the acceptable sound quality to provide relief varies amongst tinnitus sufferers, and Tyler et al.[19] suggests that a patient-specific tone may be more beneficial in providing tinnitus relief.

In this study, we were interested in studying the magnitude of tinnitus relief that results from exposure to a novel, high-frequency directional audio system. Our primary interest was to explore the change in tinnitus perception that results from use of the HyperSound system, and secondly, to determine the change in reactions to tinnitus after use of the sound therapy, and then quantifying these reactions, if possible. The HyperSound audio system would be classified as a non-wearable tinnitus sound generator (see Hoare et al.[10] for a review of non-wearable sound generators). These are typically used in specific applications, such as to fall asleep at night, working in a contained office, or while quietly reading[20]. Non-wearable sound generators have been reported clinically to provide relief from tinnitus for some patients, however, there remains little to no evidence from clinical trials on their effectiveness[10].

The HyperSound audio system was developed in 2015 by researchers and audiologists to provide improved sound clarity and speech intelligibility for individuals with hearing loss when listening to the television or stereo, as described in Mehta et al.[21]. The HyperSound audio system works different than conventional speakers and creates highly directional audible sound from ultrasonic energy using emitters and amplifiers, digital signal processing, and a patented algorithm[21]. The system works by electronically converting acoustic stimuli into an ultrasonic carrier frequency that is transmitted up to 90 kHz, above the human range of hearing. The carrier frequency is then demodulated by the air due to the nonlinear properties of air as a medium. The nonlinearity of air reproduces the ultrasonic carrier frequency into highly-directional beam of complex sound waves in the frequency range of 1.5 kHz to 16 kHz. The audible sound propagates in a focused direction along the beam, rather than as a typical point source in all directions. In doing so, the sound waves are only heard by those individuals located within the air beam, and those individuals outside the targeted area will not hear the enhanced sound at the same sound pressure level. A final feature of the HyperSound audio system is that ambient noise and reverberation effects do not degrade the acoustic signal as observed with conventional speakers because the intensity level is maintained with HyperSound over the propagation of the sound energy in the narrow air beam.

A sponsored study by Mehta et al.[21] compared the HyperSound audio system to a conventional speaker system testing speech perception abilities for ten individuals with mild-to-severe hearing loss. Speech perception was tested in the sound field using the AzBio sentence test[22] presented at 50 in quiet and 70 dB SPL in quiet and in noise, and the CNC word recognition test[23] presented in quiet at 50 and 70 dB SPL. The results revealed a significant improvement using the HyperSound system on both the AzBio and CNC tests at 70 dB, though no improvement at the lower presentation

levels. These results suggested an improvement for patients with hearing loss using the HyperSound audio system compared to conventional speakers[21].

There has been interest in using high-frequency vibration as a treatment for tinnitus *via* bone conduction[24,25]. Goldstein et al.[24] assessed the long-term benefits of an ultra-high-frequency stimulus between 10-20 kHz for 15 participants with severe tinnitus. Participants were exposed to the sound therapy *via* a bone conduction transducer for 10, 12, or 14 sessions, and tinnitus severity, masking levels, and residual inhibition were measured pre- and post-treatment. A significant change in tinnitus severity was found over the course of the treatment and for some participants, however, tinnitus loudness and annoyance ratings were not significant different[24], which limit these results.

Thus far, one small, sponsored study examined the use of the HyperSound audio system for tinnitus relief[26]. In that study, 11 adult participants with chronic bilateral or unilateral tinnitus were exposed to an acoustic stimulus for 60 minutes to determine the impact of the sound therapy on the perception of their tinnitus. Pure-tone audiometry was first conducted to program the custom equalization curve based on the NAL-RP hearing aid prescription[27] that was then inputted into the amplifier to present the stimuli. The participants selected their preferred sound, either nature sounds or broadband noise, and the signals were presented from the two emitters at a distance of 6' from the participant. Three outcome measures were included in the study: a) the Tinnitus Handicap Inventory (THI)[28], b) tinnitus loudness using a 100-point visual analog scale, and c) tinnitus annoyance using a 100-point visual analog scale. All measures were administered to the participants pre- and post-treatment (or immediately before and after sound exposure). Results revealed a significant decrease in tinnitus loudness (i.e., a 37 point reduction; $p<0.00005$) and annoyance (i.e., a 35 point reduction; $p < 0.00007$) following exposure to the stimuli[26]. Despite these significant changes in tinnitus perception, there was no significant change in THI scores after the exposure ($p=0.06$)[26]. Based on these preliminary findings, an independent, exploratory study investigating the merits of this device was deemed appropriate.

Therefore, the purpose of this study was to assess the magnitude of tinnitus relief that might occur with use of the HyperSound audio system for patients with tinnitus.

MATERIALS AND METHODS

Participants

We recruited participants who were 18 years of age or older with chronic, sensorineural tinnitus for at least six months. Participants with middle ear tinnitus, cochlear implants, or middle ear implants, or who had or were currently undergoing psychiatric treatment for related symptoms of their tinnitus were excluded from participation. We recruited participants *via* email and letter from March 2017 through June 2017 who were faculty, staff or administration at Augustana College, as well as clients who fit the inclusion criteria from the Augustana College Center for Speech, Language, and Hearing, or who were part of our research study database. In total, 24 participants (12 male and 12 female) were eligible to participate. However, one participant discontinued his participation in the study because he could not find a sound that reduced the prominence of this tinnitus during the selection of the stimuli (description as follows). Although preliminary testing was completed for this participant, the data was excluded from the analysis because of the absence of during and post-exposure measures. Demographic information for the remaining 23 participants is displayed in Table 1.

Table 1. Demographic and tinnitus background information for all 23 participants [Note: Tinnitus Pitch was rated on a numerical scale from 0-100, with 0=very low; 100=very high. Location of tinnitus: Both ears equally, 39.1%; Both ears, lateralized to one ear, 34.8%; Unilateral, 13.0%; In head, 13.0%. Cause of tinnitus: Unknown=34.8%; Aging=34.8%; Noise=26.1%; Other (Thyroid condition)=4.3%].

Variables	Mean	SD, SE	Range
Age (years)	60.1	12.1, 2.5	30-76
Tinnitus Handicap Questionnaire	23.2	20.1, 4.2	4.1-70.2
Duration of Tinnitus (years)	12.2	13.0, 2.7	0.5-52
Days in 1 mo. bothered by tinnitus	22.1	12.1, 2.5	0-31
Pitch of Tinnitus (0-100 rating)	80.2	14.1, 3.0	40-100

The average age for the 23 participants was 60 years, with a range from 30-76. The mean THQ total score for the study participants was 23.17 with a range from 4.1-70.2. Not all participants were bothered by their tinnitus, as indicated by the THQ scores and number of days bothered by tinnitus (Table 1). Overall, the average duration of tinnitus was 12 years, which varied widely from 6 months to 52 years, and 73.9% reported bilateral tinnitus, 13% had unilateral tinnitus, and 13% reported the tinnitus was in their head. The most commonly reported causes for tinnitus in this sample was unknown (34.8%) and aging (34.8%), followed by noise exposure (26.1%), and finally, one case of a thyroid condition (4.3%). Participants were compensated for their time during the study. The study was approved by the Augustana College Institutional Review Board.

Procedure

An audiogram was first obtained by testing pure-tone air and bone conduction results. This data was used to program the HyperSound amplifier for presentation of the acoustic stimuli. Results were collected in a sound-treated booth in the Hearing Lab at Augustana College using a GSI-61 audiometer and insert earphones. Conventional pure tone audiometry was performed from 125-8000 Hz in both ears for air conduction, and from 250-4000 Hz for bone conduction testing to verify the type of hearing loss. Figure 1 shows the mean air conduction hearing thresholds from 125-8000 Hz for all participants.

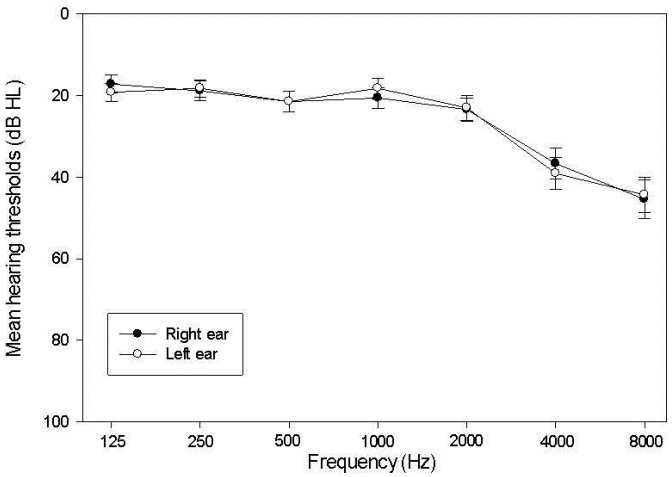

Figure 1. Mean hearing thresholds from 125-8000 Hz for the 23 participants. Filled circles represent the right ear and open circles are the left ear. Error bars represent standard error of the mean.

Following the hearing test, subjects were kept in a quiet lab space for approximately five minutes to establish their tinnitus baseline. Once all participants reported their tinnitus returned to its typical level, several questionnaires were administered. First, a tinnitus intake questionnaire consisting of 18 items was administered to each participant to document demographic and background information. The questionnaire included questions on the pitch of their tinnitus (rated from 0-100, with 0=very low, 100=very high), the cause of their tinnitus, and the typical loudness and annoyance of their tinnitus (rated from 0-100). Next, the THQ was administered to determine the handicapping nature of tinnitus for each participant before the study began (Table 1). Here, all 27 items were administered and responses were gathered using a scale from 0 (strongly disagree) to 100 (strongly agree). Additionally, the 12-item Tinnitus Primary Functions Questionnaire (TPFQ) [29] was administered to each participant. The short 12-item version was used here, which ascertained the impact of tinnitus on the participant's lifestyle, specifically in the areas of concentration, emotion, hearing, and sleep. Scores for each item were numerically rated from 0 (completely agree) to 100 (completely disagree). Lastly, the participants' tinnitus loudness and annoyance ratings were collected prior to any sound presentation. Though loudness and annoyance ratings were gathered from participants *via* the intake questionnaire, this information was regathered immediately prior to the start of the sound therapy to establish their baseline. Tinnitus loudness was rated on a numerical scale from 0 (very faint) to 100 (very loud) and annoyance of one's tinnitus was rated on a similar scale from 0 (not annoying at all) to 100 (extremely annoying).

Next, the HyperSound Clear 500P audio system was used to present the acoustic stimuli for the study. The system includes an amplifier, two emitters, and a HyperFit PC application for programming. The audio system works by digitally converting the acoustic stimulus onto ultra-high-frequencies *via* the amplifier and software, reproducing and transmitting the ultra-high frequency sounds into a narrow beam using the emitters, and finally, demodulating the signal into audible sound using the nonlinearity of the air. The set-up of the equipment is as follows. The amplifier was connected to the speakers *via* RCA audio cables. The two Polyvinylidene Flouride (PVDF) emitters were positioned next to one another on floor stands to approximate a height of 4' and a distance of 10' from the participant to ensure that the participant would be within the targeted area or beam when seated. The amplifier also interfaced *via* a USB cable with a Dell laptop to run the HyperFit application for programming the tinnitus module of the HyperSound audio system.

The pure tone thresholds for the participants were entered into the HyperFit software application that created a custom equalization curve by adjusting the equalizer settings of the amplifier from 1.5 kHz to 16 kHz in ½ octave bands. The software equalized loudness for average level inputs using the NAL-R formula[27,28] for each ear separately. There were two participants with asymmetrical hearing thresholds, with pure tone averages differing by more than 20 dB HL. In these cases of asymmetrical hearing loss, the left and right emitters were directed at the specified ear, with the amplified audio signal shaped for each ear per the NAL-R prescribed formula.

Next, the participants selected an acoustic stimulus that made their tinnitus less prominent. All nine acoustic stimuli (i.e., stream, rain, wind, fan, shower, forest, waves, white noise, and brownian noise) were presented sequentially to the participants, and participants ranked the stimuli from 0-100 based on how acceptable the sound was in decreasing the prominence of their tinnitus. The participants were instructed to select a sound that was most acceptable to have in the background, knowing that their tinnitus might still be present. The volume of the selected acoustic stimulus was also adjusted (+/- 10 dB) to the lowest level that provided the most masking or relief of the participant's tinnitus. The peak sound pressure level of the masking sounds was measured at the participants' ear level and varied between 53.0 dBA (Stream) to 60.9 dBA (Shower).

The participants were then exposed to the customized acoustic stimulus of their choice for 30 minutes. Participants were encouraged to ignore the sound and sit and read, or do some other quiet activity (e.g., knitting) to take their mind off the sound. We gathered loudness and annoyance ratings during the exposure, or after approximately 28 minutes of listening time. As with the pre-exposure ratings, tinnitus loudness was rated from 0 to 100 (very faint to very loud) and tinnitus annoyance was rated from 0 to 100 (not annoying at all to extremely annoying). Then, after 30 minutes of total exposure to the acoustic stimulus, subjects completed several questionnaires. First, tinnitus loudness and annoyance was reassessed post-exposure using the identical 0-100 scale as done with previous ratings. Next,

the 12-item TPFQ was re-administered to determine the overall impact of the tinnitus masking. Finally, participants rated the acceptability of the masker in reducing their tinnitus using a numeric rating scale from 0-100 with 0=not at all acceptable and 100=very acceptable. To examine the post-masking effects of the stimuli, we asked participants to continuously rate their tinnitus loudness in one minute intervals until it returned to its pre-trial loudness. Only those participants who experienced a reduction in their tinnitus were asked to rate the loudness of their tinnitus in this manner following exposure to the stimuli. This method for quantifying the perception of the tinnitus was performed similarly as described in previous studies [17]. Here, loudness was measured on a numeric scale from 0 to 100, from very faint to very loud, and was collected in 1 minute intervals after exposure to the stimuli. If after 10 minutes, the tinnitus had not returned to its typical loudness level, participants were allowed to leave the lab, but were asked to report the time (in minutes and hours) when their tinnitus returned to its pre-trial loudness.

Data analysis

The average tinnitus loudness and annoyance ratings across the four intervals (typical, pre-, during, and post-exposure) were analyzed using a repeated measures analysis of variance (ANOVA) test. The first condition was defined as 'typical' because the data was collected from the intake questionnaire and represents the typical loudness or annoyance of each participant's tinnitus. Follow-up tests were completed using a Bonferroni-adjustment to control for multiple pairwise comparisons. Additionally, the average pre- and post-exposure TPFQ scores for the four subscales (concentration, emotion, hearing, sleep) and total score were compared using paired t-tests. Continuous variables including the subjective ratings were reported descriptively using measures of central tendency and spread (means, ranges, and standard deviations) while categorical variables such as stimulus choices were summarized as number and percentage of the total study population. For all tests, statistical significance was defined as $p<0.05$. Statistical Package for the Social Sciences (SPSS) v. 24 was used to analyze the data.

RESULTS

Displayed in Table 2 are the stimulus choices for the participants. Of the nine stimuli, stream and waves were the most preferable sounds for tinnitus relief with 34.8% and 30.4% of the participants, respectively, choosing these two stimuli. Broadband noise and forest were selected by 13.0% of the participants, whereas rain and shower were chosen by less than 5% of the study participants. Finally, fan noise, wind, and brown noise were not chosen by any participants in this study.

Shown in Figures 2A and 2B are individual results showing the change in tinnitus loudness and annoyance during

Table 2. Frequency and relative frequency for the nine masking sounds [Note: Relative frequency represents the percentage of total participants (n=23) that chose the sound therapy stimulus].

Sound therapy stimulus	Frequency of times chosen	Relative frequency
Stream	8	34.80%
Waves	7	30.4%
White noise	3	13%
Forest	3	13%
Rain	1	4.4%
Shower	1	4.4%
Fan	0	0%
Wind	0	0%
Brown noise	0	0%

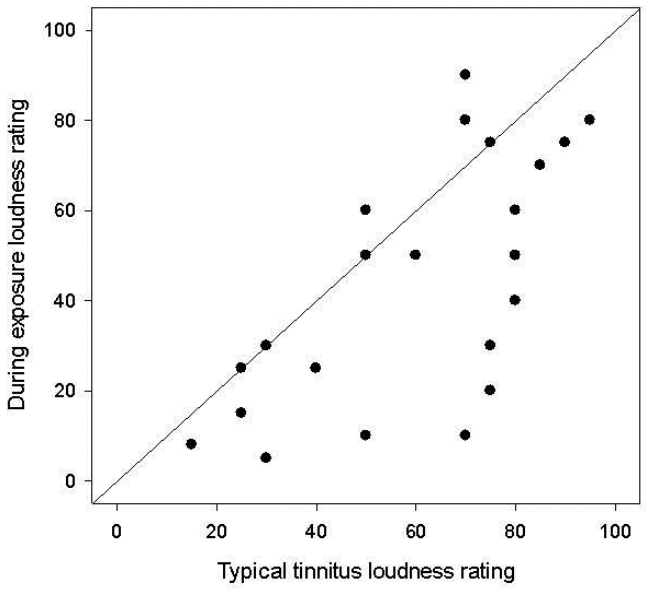

Figure 2A. shows the individual ratings of tinnitus loudness from the typical level (x-axis) to the rating during the exposure (y-axis). Ratings are from 0 (very faint) to 100 (very loud).

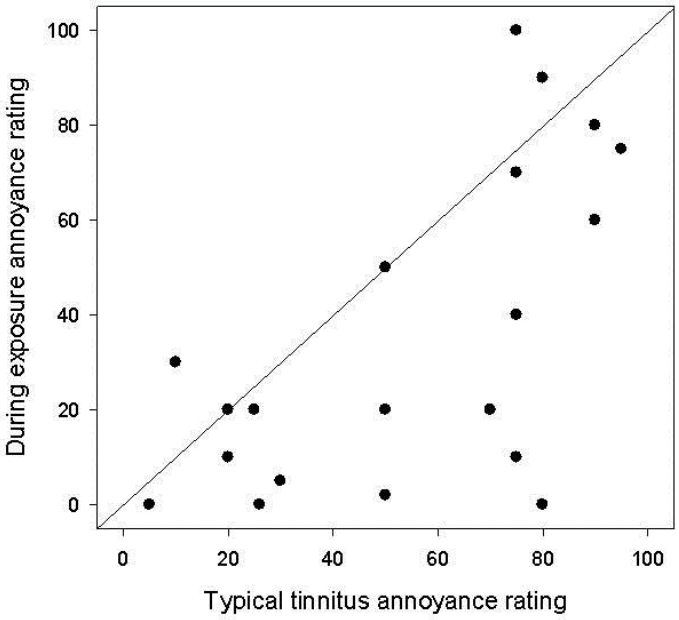

Figure 2B. shows the individual ratings of annoyance of tinnitus from the typical level (x-axis) to the level during the exposure (y-axis). Ratings are from 0 (not annoying at all) to 100 (extremely annoying).

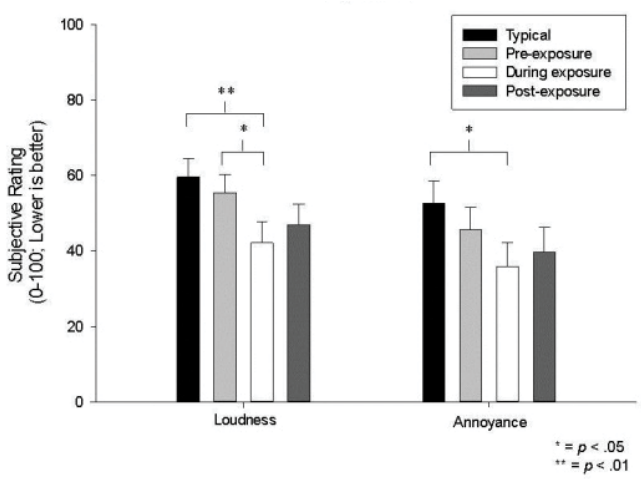

Figure 3. Tinnitus loudness and annoyance ratings shown across the four measurement intervals. Ratings for tinnitus loudness from 0 (very faint) to 100 (very loud) are shown on the left and annoyance levels from 0 (not annoying at all) to 100 (extremely annoying) are shown on the right. Black bars represent the typical levels; light gray bars are pre-exposure ratings; white bars are during exposure ratings; and dark gray are the post-exposure ratings. Significant differences are marked by *=p<0.05 and **=p<0.01.

exposure to the sound therapy compared to their typical level. A majority of the participants showed reductions in their tinnitus loudness (16/23) and annoyance (14/23) ratings during the sound exposure, with only three participants (HS 1, 8, 16) reporting an increase (or worsening) in their tinnitus loudness and annoyance.

Displayed in Figure 3 are the average tinnitus loudness and annoyance ratings across the four measurement intervals: a) typical level from the intake questionnaire, b) pre-exposure or immediately prior to sound exposure, c) during the exposure, and d) post-exposure or immediately after the sound exposure. The participants' typical and pre-exposure ratings of their tinnitus loudness approximated 60% and 56%, and dropped to 42% during the exposure and 47% after the exposure to the sound therapy. Results of the repeated measures ANOVA revealed a significant difference in the participants' tinnitus loudness across the four intervals, $F(3,66)=6.9$, $p<0.0001$. A Bonferroni-adjusted series of all possible pairwise comparisons found that tinnitus loudness was significantly different from the participants' typical level compared to their during exposure rating ($p=0.004$), and between the pre-exposure (immediately prior to the sound presentation) and during exposure ratings ($p=0.038$). There was no significant difference between the pre- and post-exposure ratings ($p>0.05$), though the difference between the typical loudness rating and the participants' post-exposure rating showed a trend towards significance ($p=0.076$). Overall, this suggests that there was a significant decrease in tinnitus loudness from the participants' typical levels while they were exposed to the sound therapy. The decrease in tinnitus loudness was observed only during the exposure to the sound therapy, and once the sound stopped, the effect was no longer observed.

For tinnitus annoyance, the typical and pre-exposure annoyance ratings were 53% and 45%, and dropped to 36% and 40%, respectively, during and after exposure to the sound therapy. Ratings of annoyance from tinnitus were between 6-10 points lower than the subjective tinnitus loudness ratings. As with tinnitus loudness, results of the repeated measures ANOVA revealed a significant difference across the four intervals in the annoyance of their tinnitus for these participants, $F(3.66)=4.6$, $p<0.006$. A Bonferroni-adjusted series of all possible pairwise comparisons found that degree of annoyance as a result of tinnitus was significantly different between the participants' typical level and their during exposure rating ($p=0.031$), with all other comparisons not significantly different. This indicates that the HyperSound sound therapy decreased the level of annoyance with tinnitus for these participants compared to their typical or usual annoyance levels. However, as with tinnitus loudness, the effect on tinnitus annoyance from the HyperSound sound was only measureable during exposure to the sound and did not persist once the exposure ceased.

Displayed in Figure 4 are the average TPFQ results comparing questionnaire responses before and after the sound exposure for the four TPFQ subscales of concentration, emotion, hearing, and sleep, and for the total score. Higher subjective ratings on this questionnaire indicate greater reactions and, therefore, more limited functioning in these areas of daily living due to tinnitus. Prior to the sound therapy, we found that tinnitus had a greater impact on concentration and hearing for these participants with ratings of 34% and 37%, respectively. By comparison, the emotion subscale had the lowest rating of 13%; therefore, emotional distress including depression and anxiety was the least problematic area impacted by tinnitus for these participants. Additionally, the total score was 27% prior to sound exposure. After exposure, the concentration and hearing subscale score decreased to

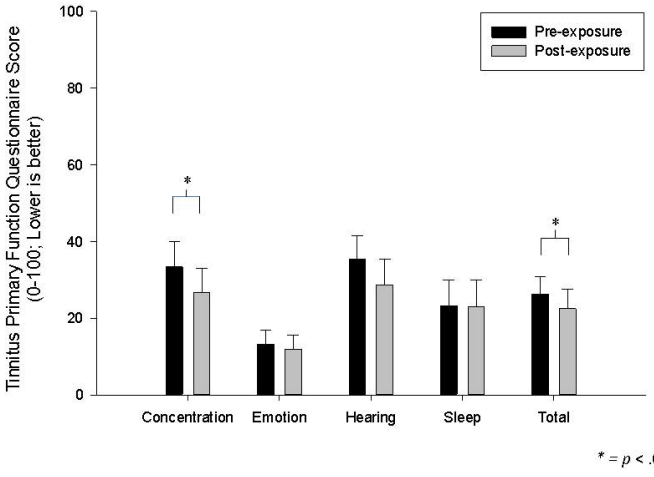

Figure 4. Responses on the tinnitus primary functions questionnaire for the four subscales (Concentration, Emotion, Hearing, Sleep) and total score. Scores are shown from 0 (strongly disagree) to 100 (strongly agree). Black bars represent the pre-exposure scores and gray represents the post-exposure scores. Significant differences are marked by *=p<0.05.

27% and 29%, respectively, with no change in the emotion score (12% compared to 13% pre-exposure). The total score also dropped to 22% after exposure. Results from paired t tests revealed that the decrease in pre- to post-exposure for the concentration subscale ($t(21)=2.411$, $p=0.03$) and the total score ($t(21)=2.462$, $p=0.02$) were significantly different, and all other differences were not significant ($p>0.05$). These results indicate that the HyperSound sound therapy significantly improved the concentration abilities of the participants while exposed to the sound. Additionally, the significant decrease in the TPFQ total score suggests that this sound therapy provided an improvement in the functional limitations of tinnitus for these study participants.

To further investigate the post-masking effects from the sound therapy, we also examined the individual data comparing their typical levels of tinnitus loudness and annoyance to their post-exposure ratings.

Shown in Figure 5, plot A are individual data showing the typical tinnitus loudness ratings on the x-axis *vs.* post-exposure ratings along the y-axis. There were three individuals (participants HS 9, 13, and 19) who experienced partial suppression of their tinnitus, or ratings changing by 40% or more with exposure to the HyperSound therapy, and one individual (HS 11) who had complete suppression of their tinnitus with loudness ratings changing by 80%. The changes in tinnitus annoyance following exposure to the sound therapy are shown in plot B of Figure 5. The greatest difference in annoyance after exposure to the sound was found for participant 11, who showed a change in annoyance of 80%. Additionally, there were five participants (HS 1, 6, 9, 15, and 19) who experienced a decrease in the annoyance of their tinnitus of at least 25%.

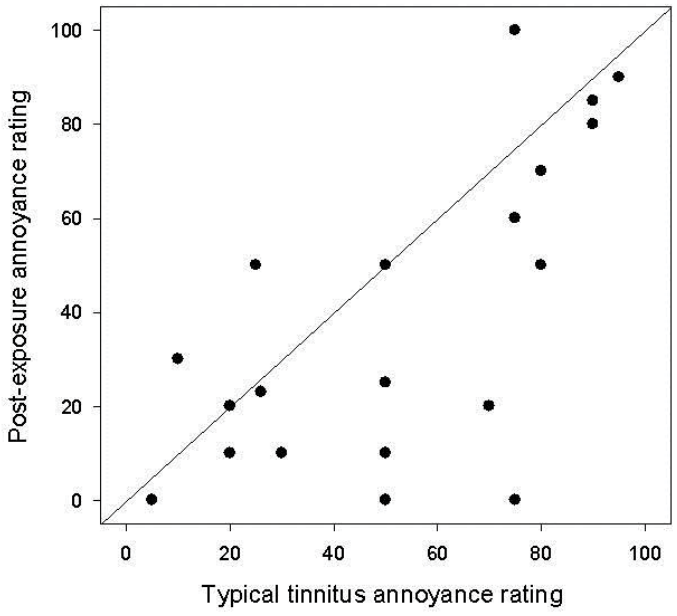

Figure 5. Plot A shows the individual ratings of tinnitus loudness from the typical level (x-axis) to the post-exposure rating (y-axis). Ratings are from 0 (very faint) to 100 (very loud). Plot B shows the individual ratings of annoyance of tinnitus from the typical level (x-axis) to the post-exposure level (y-axis). Ratings are from 0 (not annoying at all) to 100 (extremely annoying).

Based on our analysis quantifying the perception of the tinnitus in one minute intervals following cessation of the stimuli, the results revealed that seven participants (HS 6, 9, 11, 13, 19, 20, & 22) reported a decrease in the loudness of their tinnitus. These data showed that, on average, 36 minutes elapsed between the end of the presentation of the stimulus and the return of the tinnitus to its typical level for this subgroup of participants. The post-masking effect on the loudness of their tinnitus varied significantly between participants from 1 minute for participant HS 22, to 2½ hours for participant HS 19.

Finally, for acceptability of the masker sound as a treatment for tinnitus, results revealed that 71.96% of the participants (Median=80; SD=33.67; SE=7.02) found this to be acceptable. Only four individuals (HS 1, 4, 14, and 16) reported that HyperSound was not an acceptable treatment for tinnitus, with ratings poorer than 50%. These results indicate that, for the majority of the participants in this study, sound therapy using the HyperSound audio system was helpful in decreasing the prominence of their tinnitus.

DISCUSSION

This study was intended as a preliminary step to determine if there might be any merit in providing a high-frequency sound therapy for tinnitus. Though there have been previous reports using the Hypersound audio system, these reports were sponsored studies, and limited by lack of independent evaluation. The HyperSound audio system utilizes two emitters and digital signal processing to create a highly directional beam of sound up to 16 kHz, and was implemented here to expose tinnitus patients to a customized sound therapy for 30 minutes. Tinnitus loudness and annoyance ratings were gathered at several intervals throughout the study, and questionnaires were administered pre- and post-exposure to determine the impact of the system on the participants' tinnitus. The results revealed that the HyperSound Tinnitus Module reduced tinnitus loudness for 16 of 23 participants and tinnitus annoyance for 14 of 23 study participants. This reduction was significant when patients rated the loudness and annoyance of tinnitus while being exposed to the sound compared to their typical levels. However, once the sound therapy ended, tinnitus loudness and annoyance ratings were not significantly improved compared to pre-exposure ratings. In addition, we found a greater reduction in tinnitus loudness with use of the sound therapy than in tinnitus annoyance, with significant differences emerging in loudness levels from both pre-exposure levels and typical levels. Though these results were generally positive, there were three participants (HS 1, 8, 16) who reported an increase in their tinnitus loudness and annoyance during exposure to the sound therapy.

Overall, these results suggest that high-frequency sound might be helpful in alleviating tinnitus for many tinnitus sufferers. The previous Mehta et al. found a significant reduction in subjective ratings pre- to post-exposure for tinnitus loudness (a 37 point reduction) and annoyance (a 35 point reduction). The pre-exposure ratings in our study were similar for tinnitus loudness and annoyance at 60% and 53% compared to 60 and 64% for Mehta et al. respectively. However, the post-exposure ratings for tinnitus loudness and annoyance, though statistically significant, were higher in this study at 42% and 36%, compared to 23% and 29% for Mehta et al. One reason for this difference in subjective ratings is likely related to the duration of the exposure, which was longer at 60 minutes in Mehta et al. and only 30 minutes in the present study[26].

The clinical practice guideline for managing tinnitus[11] reports that, overall, the evidence for sound therapy devices is lacking and does not show a clear improvement in tinnitus severity and tinnitus-related symptoms from sound therapy. However, sound therapy was recommended in the clinical practice guideline as an option for patients because there are many patients that clinically report improvements in tinnitus loudness and annoyance with sound therapy. This study found an improvement in tinnitus loudness and annoyance during the sound exposure interval based on the group data, and brings more evidence to this recommendation that the tinnitus perception may be decreased when high-frequency sound is used for tinnitus relief. It is also important to emphasize that no counseling or education was provided to the participants during this study, and only when the study procedures were finalized was informational counseling provided as an overview of potential treatments that might benefit the patient.

Further, based on responses to the concentration subscale and total score on the Tinnitus Primary Functions Questionnaire, this study found an improvement pre- to post-treatment in the participants' concentration or attention abilities and functional impact of tinnitus. We did not observe a significant change in emotional distress, hearing abilities, or sleep, when comparing results on these subscales pre- to post-exposure. This result is not surprising, however, given that our participants were exposed to the sound therapy in a single, 30-minute session. If we had provided an at-home trial or other method of long-term exposure to assess the degree of tinnitus relief using the sound therapy system, we might have seen additional improvements in these areas of life impacted by tinnitus as well. In our study, we found a significant improvement in the total scores on the TPFQ responses averaging 27% and 22% pre- and post-exposure, which was also observed by the 100 participants with scores changing from 51% to 38% following treatment[29]. In that study, participants were tested before and after receiving either counseling or counseling and sound therapy, whereas in this study, only sound therapy was used as a method of treatment. Similar to Tyler et al.[29], the highest mean scores from our participants were reported on the concentration and hearing subscales. In sum, this suggests that even for a group of participants who are less bothered by tinnitus, significant improvements were found in the concentration abilities and in the functional impact of tinnitus when this type of sound therapy is used to treat tinnitus.

Here, we found a variety of different responses from the participants in how tinnitus loudness changed with exposure to the sound therapy. Five different post-masking responses were introduced by Tyler et al.[17] based on their study of the perception of tinnitus following the termination of a masker in 10 subjects. In our study, we found two participants with complete suppression of tinnitus (HS 11, 19) after cessation of the masker, while the majority of participants showed a reduction in the tinnitus loudness, both not full suppression of their tinnitus (HS 3, 5, 6, 9, 13, 15, 18, 20, 22, 23). Moreover, many of our participants reported no change in their tinnitus (HS 1, 2, 7, 12, 14, 21, 24) once the masker stopped, while four reported that their tinnitus increased in loudness briefly after the stimuli terminated before returning to its original level (HS 4, 6, 8, 16). Thus, as recommended by the clinical practice guidelines for managing tinnitus[11], it is important to examine the individual responses before embracing this as a treatment option for any given patient. Though we saw reductions in tinnitus loudness with sound therapy based on the average data, an improvement was not universally observed in all patients. In sum, these results indicate that sound therapy has a variety of effects on one's tinnitus, with some patients benefitting from sound therapy, but not all.

There are several limitations in this study that should be mentioned. First, we recruited a small sample of patients with chronic, sensorineural tinnitus, but had lower scores on tinnitus severity and handicap compared to previous studies[14,29]. Despite the fact that our participants were less bothered by their tinnitus, the results revealed improvements in tinnitus loudness and annoyance compared to their typical levels, and in the functional impact of tinnitus. Interestingly, for the three participants with high scores above 60% on the Tinnitus Handicap Questionnaire and Tinnitus Primary Functions Questionnaire, we did not observe a reduction in tinnitus loudness and annoyance as resulted for most of the participants in this study. Also, this study did not incorporate a control group or compare to other more common clinical treatments for tinnitus, so conclusions about the effectiveness of HyperSound for tinnitus relief must be made with caution. Therefore, it is difficult to draw any firm conclusions about the effectiveness of HyperSound until a controlled trial is completed with a larger sample size and a control group.

Additionally, in this study, we relied on subjective self-report to measure the change in tinnitus perception

and the reactions to tinnitus consistent with our aim, as opposed to psychoacoustic measures of tinnitus such as loudness-matching or minimum masking levels. Future studies of the HyperSound audio system should use these psychoacoustic metrics to investigate the effectiveness of the sound therapy. Finally, there was some variability in hearing thresholds across our study group. The average hearing loss shown in Figure 1 was a mild sloping to moderate, high-frequency hearing loss. However, there were two participants with asymmetrical hearing thresholds (HS 3, 21), and we attempted to control for this variable by programming the acoustic stimuli in the HyperSound software using the NAL-RP prescriptive formula based on the individual hearing configuration of the participant. For patients with tinnitus, this type of sound therapy could quite easily be incorporated into one's home or office to provide a background sound while they are attending to other tasks or simply reading, as was done here. We found an improvement in concentration abilities, which suggests that if this was used at home or while working, it could potentially distract the individual from their tinnitus sound and allow for better concentration on the task at hand. Currently, there are many new technological advances in audio devices, including personal stereo systems that connect with TVs, laptops, etc., that could incorporate a similar sound therapy for patients with tinnitus.

Further, we found that acceptability of this sound therapy was high, with the majority of participants reporting that this was an acceptable treatment option. Compliance and ease of use was also good throughout the study and only one individual was not willing to continue during the study because of no change observed in his tinnitus when listening to the sound stimuli. The instructions for use are straightforward and include sitting approximately 10 feet away from the speakers and making sure that the listener can see their reflection in the speaker to ensure the best reception of the audio signal. The system can be programmed ahead of time by the audiologist or hearing health professional, so that the patient only needs the two emitters and an amplifier to operate their device. Finally, the Hypersound audio system is priced at approximately half the cost of a combination hearing aid/masker device, making it a cost-effective solution for tinnitus relief. Despite these generally positive results, more research is needed to determine the effectiveness of the HyperSound audio system compared to clinical treatments for tinnitus.

ACKNOWLEDGEMENTS

The work was supported by the Faculty Research Grant and a Summer Research Stipend from Augustana College awarded to Ann Perreau. We would like to thank Brian Taylor from Turtle Beach Corporation for providing direction during the development of this study and for supplying the HyperSound audio system, Haihong Ji for her contributions on the data analysis, and lastly, the participants from Augustana College who participated in this study.

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