

# Effects of Acoustical Stimuli Delivered through Hearing Aids on Tinnitus

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## Abstract

**Background:** The use of acoustic signals to mask, mix with, or ease the distress associated with tinnitus has been clinically employed for decades. It has been proposed that expanding acoustic options for tinnitus sufferers due to personal preferences is desirable. Fractal tones incorporate many useful characteristics of music while avoiding certain features that could be distracting to some individuals.

**Purpose:** To assess the effects on relaxation, tinnitus annoyance, tinnitus handicap, and tinnitus reaction from the use of a hearing aid that incorporates combinations of amplification, fractal tones, and white noise.

**Research Design:** Participants listened to experimental hearing aids containing several acoustic options and were asked to rate the signals in terms of their effect on relaxation and tinnitus annoyance. They subsequently wore the hearing aids for 6 mo and completed tinnitus handicap and reaction scales.

**Study Sample:** Fourteen hearing-impaired adults with primary complaints of subjective tinnitus.

**Intervention:** Participants were tested wearing hearing aids containing several programs including amplification only, fractal tones only, and a combination of amplification, noise, and/or fractal tones. The fractal tones (now commercially available as the “Zen” feature) were generated by the Widex Mind hearing aid. Rating procedures were conducted in the laboratory, and tinnitus reaction and handicap were assessed during and following a 6 mo field trial.

**Data Collection and Analysis:** Data were collected at the initial visit, one week, 1 mo, 3 mo, and 6 mo. Nonparametric statistics included Wilcoxon matched-pairs signed-rank,  $\chi^2$ , and repeated-measures analyses of variance.

**Results:** Thirteen of 14 participants reported that their tinnitus annoyance, as measured by the Tinnitus Annoyance Scale, was reduced for at least one of the amplified conditions (with or without fractal tones or noise), relative to the unaided condition. Nine assigned a lower tinnitus annoyance rating when listening to fractal tones alone versus the amplification-alone condition. There was a range of preferences observed for fractal settings, with most participants preferring fractals with a slow or medium tempo and restricted dynamic range. The majority (86%) indicated that it was easier to relax while listening to fractal signals. Participants had preferences for certain programs and fractal characteristics. Although seven participants rated the noise-only condition as providing the least tinnitus annoyance, only two opted to have noise only as a program during the field trial, and none selected the noise-only condition as the preferred setting. Furthermore, while all four of the experienced hearing aid users selected noise as producing the least annoying tinnitus in the laboratory, only one selected it for field wear. Tinnitus Handicap Inventory and Tinnitus Reaction Questionnaire scores were improved over the course of the 6 mo trial, with clinically significant improvements occurring for over half of the participants on at least one of the measures.

**Conclusions:** The results suggest that use of acoustic stimuli, particularly fractal tones, delivered through hearing aids can provide amplification while allowing for relief for some tinnitus sufferers. It is important to

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recognize, however, that tinnitus management procedures need to be supplemented with appropriate counseling.

**Key Words:** acoustic stimulation, counseling, fractal tones, hearing aids, music, music therapy, relaxation, tinnitus

**Abbreviations:** THI = Tinnitus Handicap Inventory; TRQ = Tinnitus Reaction Questionnaire; TRT = tinnitus retraining therapy

As with many digital technologies, hearing aids have evolved and are being used for other than their primary purpose, including as wireless connections to telephones, televisions, and MP3 players and use as sound-level meters and even audiometers. It is only natural that the potential application of acoustic stimuli be explored for utilities in addition to enhancing communication and assessing the acoustic environment for the hearing impaired. For example, it is known that there are many nonauditory and psychological ramifications from hearing loss that may lead to feelings of isolation, paranoia, depression, anxiety, and stress (Kochkin and Rogin, 2000; Kochkin, 2005). The incidence of increased stress is reportedly higher in people with hearing loss than for the normal-hearing population (Fellinger et al, 2007). Relieving these components via sound therapy could be beneficial for hearing-impaired people.

An example of an auditory disorder that is highly influenced by stress is tinnitus. The vast majority of individuals with chronic tinnitus show at least some degree of hearing loss (Ratnayake et al, 2009). Current theories about tinnitus generation and the emotional distress associated with it suggest that the tinnitus perception may result, at least in part, because of the peripheral attenuation of auditory input (Kaltenbach et al, 2005). This attenuation provokes an increase in central auditory system activity from the dorsal cochlear nucleus through the auditory cortex, as well as a coupling with the limbic system (particularly the hippocampus and amygdala) via collateral connections from the thalamus and other structures (Eggermont and Roberts, 2004). Stimulation of the thalamus results in release of neurotransmitters, including adrenaline, to produce an autonomic nervous system response associated with stress (Swanson, 1987).

The use of music for setting and altering moods, arousing and relaxing, is certainly not new. Music is commonly put to use in homes, work environments, celebrations, advertisements, romances, movies, athletic locker rooms, shopping malls, and hospitals to soothe, relax, energize, and engage. Additionally, music has been actively, and increasingly, employed as a therapeutic treatment for a number of physical and psychological ailments (Koelsch, 2009). Advances in neuroscience and neural imaging have provided a greater understanding of the effects of musical stimuli on the brain and human behavior including stress.

Knowledge about the site of stimulation, neural interactions, and transfer of neural transmitters helps explain the behavioral consequences, both positive and negative, of exposure to music. Burns et al (1999) report that listening to music can result in physiologic changes correlated with relaxation and stress relief. Music is believed to be helpful in reducing stress because of the wide range of neural structures that are activated, including the cerebellum, frontal lobe, limbic system, and auditory cortex. Studies have shown that listening to certain types of musical stimuli induces relaxation and heightened concentration in some individuals but not in others (Furnham and Allass, 1999). Patterns of musical elements such as slower tempo, lower pitch, degree of repetition, and lack of emotional content have been established as having a calming rather than alerting effect (Hevner, 1933, 1936; Bella et al, 2001). Active listening tends to arouse; passive listening tends to soothe. Active listening tends to distract; passive listening may allow for increased relaxation and cognitive function.

A variety of acoustic stimuli have been used for tinnitus relief. Masking, popularized by Vernon (1977), employs use of a narrow band of noise centered around the perceived pitch of the tinnitus in an attempt to provide relief by either completely or partially obscuring the patient's perception of the tinnitus. While this was once considered the most common form of acoustic tinnitus management, other stimuli are now being increasingly recommended, utilized, and researched for their long-term benefits. As stated earlier, it is believed that in the case of tinnitus, central gain is increased because of peripheral attenuation (Eggermont and Roberts, 2004; Kaltenbach et al, 2005, Parra and Pearlmutter, 2007). Providing sound stimulation via amplification or other means to overcome the lack of stimulation to the auditory cortex in certain damaged frequency regions can be useful in reducing the need for this additional "gain." Several studies have demonstrated relief provided by amplification (Saltzman and Ersner, 1947; Surr et al, 1985), and hearing aids are widely used as part of clinical treatment of tinnitus (Searchfield, 2005; Kochkin and Tyler, 2008). Additionally, auditory signals can mask or mingle with tinnitus, making it less perceptible. Vernon (1977) has further advocated white noise, pink noise, and narrow bands of noise, in isolation or in combination with amplification, to reduce tinnitus perception. Some advocates of

behavioral retraining therapies, as discussed below, consider masking the tinnitus to be counterproductive, since for long-term habituation to occur, the stimulus has to be perceived during training (Jastreboff, 2000).

Given the evidence that many forms of tinnitus are associated with decreased peripheral stimulation and increased limbic system activity (stress), two popular current management procedures for tinnitus sufferers, tinnitus retraining therapy (TRT [Jastreboff and Hazell, 1993; Hazell, 1999; McKinney et al, 1999]) and the Neuromonics acoustic desensitization protocol (Davis et al, 2007; Davis et al, 2008), use an educational counseling approach combined with sound therapy to help reduce the brain's need to seek the acoustic stimulation that it is missing. TRT stresses the need for avoidance of silence by using any form of incoming sound (e.g., white noise or amplification) to "mix" but never "mask" the tinnitus during all waking hours. The Neuromonics approach uses purportedly relaxing music that is filtered to compensate for hearing loss and delivered via high-fidelity earphones for a recommended 2 to 4 hr per day for approximately 6 mo.

While each of these approaches has been shown to be beneficial for certain patients, none is universally effective. A potential shortcoming of the TRT approach is that the incoming acoustic stimulus may lack the inherent stress-reducing and relaxation-inducing characteristics of music. A potential limitation of the Neuromonics procedure is that while the system modifies the musical signal to compensate for hearing loss, it only provides this stimulation during the limited time it is worn each day. It does not provide amplification of external stimuli to compensate for hearing impairment. Also, because somewhat visually obtrusive headphones are used, some patients may not be able to use the processor at times when headphones may be considered inappropriate, such as during work. Many patients have indicated to us that this would pose a problem for them.

Henry, Rheinsburg, and Zaugg (2004) hypothesized that the effectiveness of treatment can be improved by expanding the auditory stimulus options available to patients. With regard to the acoustic stimuli selected for providing relief to tinnitus patients, there are clearly individual preferences. They demonstrate this by comparing a number of stimuli, including seven filtered noises (Moses-Lang CD, Oregon Hearing Research Center, Portland, OR) and environmental sounds that were filtered and amplitude modulated (Petroff Dynamic Mitigation DTM 6a CDs, Petroff Audio Technologies, Palmdale, CA).

Both the TRT and the Neuromonics approaches emphasize the need for "passive" listening as opposed to "active" listening. This is done in order to capitalize on the natural ability of the brain to habituate to a non-

salient, nonthreatening stimulus, as well as on the fact that few people have the luxury of actively engaging in a therapeutic approach for much of their waking hours. Furthermore, it is known that sounds affect people in different ways, due to inherent and learned preferences (Hann et al, 2008). Some general statements can be made about preferences. For example, for relaxation, music with a rhythm approximating a natural resting heart rate (60–80 beats per minute) is useful. This principle is utilized in the Neuromonics approach by its careful selection of the limited number of musical passages that are played by the processor. In addition, there are individual preferences for musical styles that also merit consideration. There are potential advantages of being able to manipulate the musical parameters mentioned earlier. For example, lower pitches tend to be more calming than higher pitches. Research has shown that the use of previously recorded music may have restrictions on stress reduction because familiar music can evoke memories and potentially negative emotions (Hann et al, 2008) and create unwanted distraction. Thus, it can be argued that the use of music for subconscious relaxation and reduction of stress, as may be present in tinnitus, should not be actively distracting. And since there are personal preferences, neutral music should not have emotional associations. It is thus potentially beneficial to use relaxing background sounds to stimulate the parasympathetic division of the autonomic nervous system and to avoid exposure to negative or annoying sounds that activate the sympathetic division.

An alternative approach that incorporates the benefits and rules of music but avoids these potential limitations is the use of fractal tones. Auditory fractal tones utilize harmonic but not predictable relationships and are generated by a recursive process where an algorithm is applied multiple times to process its previous output (Hsu and Hsu, 1990; Beauvois, 2007). The tones (which sound somewhat like wind chimes) are pleasant but are not associated with music that the listener may hold in memory. The potential application of fractal tones delivered via high-fidelity hearing aids was explored. The hypothesis was that the fractal tone signal is effective in relaxing the tinnitus sufferer, as well as reducing the annoyance of tinnitus.

An experiment was conducted to determine if the presence of various acoustic stimuli, including fractal tones, delivered through a hearing aid would (1) be perceived as relaxing to tinnitus patients, (2) reduce short-term tinnitus annoyance, and (3) lower the subjective tinnitus handicap and reaction ratings. The protocol allowed for a comparison of fractal tones alone, fractal tones combined with amplification, broadband (white) noise alone, white noise mixed with amplification, and fractal tones along with amplification and white noise.

## METHOD

### Participants

A total of 14 participants (nine male and five female), ranging in age from 34 to 72 yr, completed the study. A power analysis based on a pilot study indicated that this number of participants would be an adequate sample size to yield a power of 0.8. The pilot study was based on 10 tinnitus patients with mild to moderate sloping hearing loss. Procedures were similar to those described in this article. A paired-samples *t*-test was used in the power analysis for a tinnitus handicap scale obtained at prefit (baseline) and 1 mo postfit. Based on the results obtained in the pilot study, 13 participants were determined to be required in order to achieve power of test = 0.8 for this study so that the mean score at 1 mo postfit could be established as significantly better than the mean baseline.

All participants in this study had sufficient hearing loss to warrant the use of amplification, but their primary presenting complaint was tinnitus, rather than hearing impairment. All of the participants had tinnitus for at least 1 yr and had received evaluation and treatment including extensive tinnitus counseling at the University of California, San Francisco (UCSF), Audiology Clinic by audiologists trained and experienced in tinnitus patient management at least 3 mo prior to the start of this study. The specific counseling employed was an eclectic combination of a number of approaches (Sweetow, 1986, 2000; Henry and Wilson, 1996; Jastreboff, 2000).

Participants were not allowed to begin any new medication or other treatments during the investigation that may have altered progress in either a positive or negative direction. In addition, any subject displaying cognitive deficits that might prevent the completion of the objective and subjective measures as well as the counseling were excluded. Participants had to be able to read and understand the English language well enough to complete the test measures discussed below. Participants reporting or displaying mental health issues requiring attention (severe depression, suicidal ideation) were excluded from the study and immediately referred to an appropriate mental health professional.

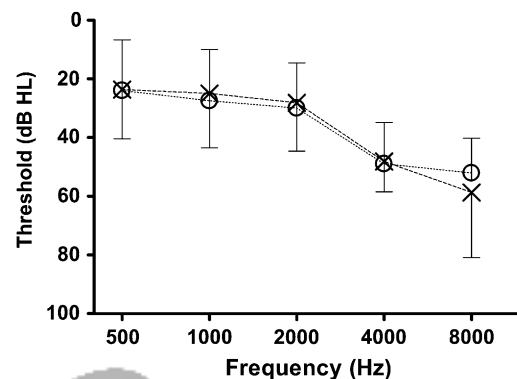
Sixteen participants were enrolled, with 14 completing the study. One participant dropped out because he was a musician and audiophile and he considered the fractal tones and sound quality of hearing aids to be annoying, and one other participant lost the hearing aid used in this experiment and chose not to continue. Data from these two participants are not included in the analysis. Four of the 14 participants were current or previous users of nonlinear hearing aids, while the

remaining 10 had not yet tried amplification for a variety of reasons including inadequate finances, lack of motivation due to minimally perceived hearing loss, and desire to delay trial with hearing aids following tinnitus counseling in order to determine if amplification purchase would still be necessary. Hearing loss ranged from mild to moderately severe. The means and standard deviations of hearing thresholds are shown in Figure 1.

Study participants were given nominal payment for their time and reimbursed for parking. All participants signed an informed consent approved by the Institutional Review Board prior to their participation.

### Questionnaires

Subjective tinnitus severity was assessed using two standardized outcome measures, the Tinnitus Handicap Inventory (THI [Newman et al, 1996]) and the Tinnitus Reaction Questionnaire (TRQ [Wilson et al, 1991]). The reason both measures were included was that each assesses a slightly different domain of an individual's response to the perception of tinnitus. The THI is a scale consisting of 25 items requiring an answer of yes (4 points), sometimes (2 points), or no (0 point). Thus, scoring can range from 0 to 100 points. The minimum THI score considered clinically significant is 20 (Newman et al, 1998). THI scores for the experimental participants ranged from 24 to 98 (mild to severe). The TRQ is a questionnaire consisting of 26 items designed to determine the effects of tinnitus on a subject's lifestyle, general well-being, and so on. The test ranges from an answer of not at all (0 points), to infrequently (1 point), to some of the time (2 points), to most of the time (3 points), to almost all the time (4 points), with a possible score of 0–104 points. TRQ scores for the experimental participants ranged from 16 to 92. Since the TRQ publications do not specify minimum levels of clinical significance, participants were excluded if their THI scores were less than 20 in order to ensure that



**Figure 1.** Mean hearing thresholds and standard deviations of test ears.

participants' reactions to tinnitus reflected significant tinnitus distress. Participants were recruited either by their clinician or by a letter describing the study.

It should be noted that the participants in this study may have been more negatively impacted by their tinnitus than those used in other investigations. For example, our participants had a mean TRQ baseline of 52.6, as opposed to the Davis et al (2007) participants' mean baseline TRQ score of 39.3. Thus, the mean TRQ level corresponds with a moderate to severe level of tinnitus disturbance, relative to the normative data collated by the TRQ's authors, in which the 50th, 75th, 90th, and 95th percentiles of a diverse population of 156 tinnitus clinic patients were represented by TRQ scores of 27, 47, 60, and 72, respectively (Wilson et al, 1991). A further indication that the majority of the participants in the current study were considered "difficult" tinnitus cases was that they presented with THI scores that were higher than average for the UCSF tinnitus clinic, and most had THI scores that were unchanged following counseling (paired *t*-test,  $p = .8$ ). This unexpected and unusual lack of change following counseling among the subjects was likely due to the fact that there was some "self-selection" involved in this population; that is, those patients who improved following counseling were not likely to return to the clinic, thus preventing their recruitment by their clinician. Additionally, if recruited patients had perceived improvements in their condition following treatment, they would not be likely to enroll because they would not consider the required time commitment to be worthwhile.

All participants were asked to complete the Tinnitus Annoyance Scale (Henry et al, 2004). This seven-point scale requires a response of 0 to 6, where 0 indicates no annoyance and 6 indicates "extreme annoyance." This scale was used to assess tinnitus annoyance while listening to different stimuli while the participant was in the laboratory setting.

## Procedures

All visits were completed at UCSF. There were a total of five visits over the course of 6 mo. At the first visit participants were given a thorough audiologic and tinnitus evaluation and completed several questionnaires including the UCSF Tinnitus Clinic Intake, Tinnitus Handicap Inventory, and Tinnitus Reaction Questionnaire. Participants reviewed the study with the research team and signed consent forms.

The Widex Mind 440 was selected for this project because it contains an optional listening program containing fractal tones. This device is a 15-channel, wide dynamic range compression hearing aid with a compression threshold as low as 0 dB HL. Among the features are an adaptive multichannel directional microphone, noise reduction, active feedback cancella-

tion, data logging, and a linear frequency transposition algorithm. The latter feature was not activated during the study. The hearing aid had the option to include amplification alone, fractal tones (called the "Zen" feature by Widex), and white noise. Each of these options could be used independently or in combination, with the microphone amplification turned on or off. The fractal program was initially designed as an optional listening program that might provide a relaxing listening background and was not marketed by the manufacturer as a tinnitus management product. However, given the nature of fractal tones and the relationship between stress and tinnitus distress, it seemed logical to explore this type of stimulus for tinnitus relief. In addition to the primary amplification program (hereafter referred to as the "master" program) and the fractal and noise options, participants had the option of additional programs for alternative situations, for example, comfort in noise or music.

There were five different default fractal styles or patterns that the participants could select. Four of the styles (designated as green, aqua, coral, and lavender) were tonal in nature (fractal), while the fifth included tones and/or a broadband noise. The fractal styles differed in their combination of major/minor notes as well as their tempo and pitch combinations. Table 1 provides a general description of each of the four tonal fractal styles. Within each style, the clinician and the wearer could also adjust the intensity, pitch, and tempo of the tones so the signal could be the most desirable for the wearer. Consequently, even if the default tones were not considered to be the most desirable, the researcher and the subject could adjust the parameters in order to optimize the preference. The various programs were accessible via a remote control device.

Compass v4.542 beta software was used with NOAH-link to program the devices. Postauricular hearing aids were fit using in situ thresholds and coupled with m-élan ear sets using an open dome, Widex vented "passion gum drops," or vented flex CAMISHA shells, depending on the preference and audiometric needs of the participant. Eleven of the 14 participants were fit binaurally. Of the three monaural fittings, two had unilateral hearing loss and the third had a profound hearing loss in the contralateral ear. A feedback test was conducted to estimate the default feedback path and to ensure optimal gain for use. The default gain settings of the hearing aid were initially used. Verification of the fitting was achieved by examining the frequency-output curve, probe microphone measures using speech mapping and the AudioScan Verifit, and simulated aided thresholds to establish audibility and comfort. At the initial fitting visit, only the "master" amplification program (no fractals or noise) was activated.

**Table 1. Acoustic Characteristics of the Four Fractal (Zen) Styles Available in the Widex Mind 440**

Fractal Style	Default Pitch			Tonality		Dynamic Range		Default Tempo			
	Low	Medium	High	High and Reverberant	Major	Minor	Restricted	Broad	Slow	Medium	Fast
Aqua	XXX				XXX		XXX		XXX		
Coral		XXX				XXX		XXX	XXX		
Lavender		XXX			XXX			XXX			XXX
Green				XXX	XXX		XXX			XXX	

Participants returned for the second visit after at least one week of hearing aid use, and the additional listening programs (three programs of the fractal tones or noise) were added. With the hearing aids connected, the participant listened to the fractal styles at the default settings in a counterbalanced order and rated the perceived relaxing qualities of each signal. Each fractal style was presented for at least 10–15 sec or until the participant was able to reach a decision. A five-point semantic differential scale was used for rating:

### RELAXATION RATINGS

- 1—very relaxing
- 2—somewhat relaxing
- 3—neutral, neither relaxing nor tensing
- 4—somewhat tensing
- 5—very tensing

The style that was rated the highest was further fine-tuned to adjust tempo and pitch in an attempt to make it more relaxing. If several styles were rated the same, participants were asked to select the one that they preferred the most. The tempo and pitch settings were adjusted using a paired comparison format to arrive at the optimal settings. Afterward, participants again rated the adjusted fractal program. The seven-point Tinnitus Annoyance Scale was then administered for the adjusted settings, allowing for relaxation ratings and tinnitus annoyance ratings for each of the listening programs.

The listening programs were set in the following manner. All participants had a master program and a program that contained master + the preferred fractal setting. Other optional settings included master + noise, noise alone, fractal alone, or master + fractal + noise. Participants also could opt to have programs set for meeting specific needs, such as music listening and comfort in noise. With the exception of the master program, the location (order) of the programs was counterbalanced.

For each listening program the gain or level setting of the fractal and/or noise stimuli was adjusted to a soft level that was audible to the participant but not so loud as to interfere with comfortable listening or speech

intelligibility. Each program was activated for at least 1–3 min before a decision was made by the participant. Participants were taught how to activate different listening programs with a remote control. Practice was provided to ensure understanding.

Participants were given instructions to use the different programs in a variety of daily listening situations. Participants were also instructed to listen to the stimuli while relaxing for 15–30 min each day by turning on the fractal tone program, remaining in a comfortable and quiet position, and focusing their attention on the sounds.

Participants returned for their third visit 1 mo later. At this visit, the data log was downloaded and reset. In addition, participants talked about their observations and experiences with the different programs. The THI and TRQ were again administered.

At the fourth visit (approximately 3 mo later), the data log was again downloaded and reset, and all questionnaires were administered. The fifth and final visit took place after 6 mo. The data log was recorded. Tinnitus participants again completed the questionnaires for the unaided condition, master program, and each fractal style.

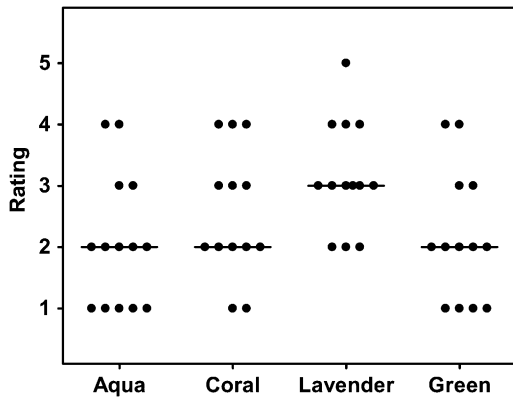
The study hearing aids were returned at the conclusion of the study. If the participants chose to purchase the devices as patients, they were given a courtesy discount.

### RESULTS

Results are described below with respect to the effects on relaxation, fractal quality preferences, tinnitus annoyance, and tinnitus handicap and reaction.

#### Relaxation Ratings

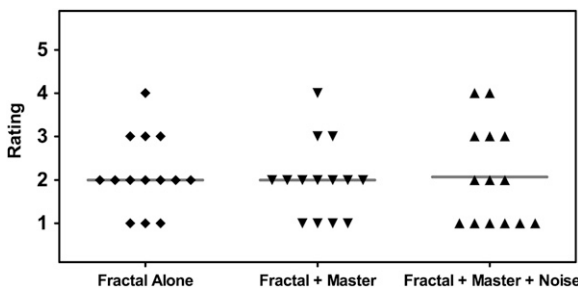
Following introduction of the fractal tones (visit two), participants were asked to assign a relaxation rating on a 1–5 scale, with 1 being very relaxing and 5 being very tensing, when using the various fractal settings. Figure 2 depicts the results. Lavender was rated approximately neutral, while the other three fractal programs were rated “somewhat relaxing.”



**Figure 2.** Relaxation ratings for the four default fractal settings. Lower numbers indicate that the participant perceived the fractals as being more relaxing. The horizontal bars reflect the median ratings. 1 = very relaxing, 2 = somewhat relaxing, 3 = neither relaxing nor stressful, 4 = somewhat tensing, 5 = very tensing.

The nonparametric related-samples Wilcoxon signed-ranks test showed that lavender was significantly less relaxing than the other three fractal programs ( $p < .05$ ), and three of the four fractal signals were rated significantly more relaxing than neutral ( $p < .05$ ). As a comparison, a small group of nontinnitus participants ( $N = 6$ ) was also asked to rate the fractal settings based on relaxation. These participants similarly found the green ( $N = 4$ ) and the aqua ( $N = 2$ ) fractal settings to be most relaxing; there was no difference between the nontinnitus and tinnitus groups' preferred fractal settings ( $\chi^2, p > .05$ ).

Figure 3 shows the relaxation ratings for fractal alone versus master + fractal versus master + fractal + noise when the preferred fractal program had been self-adjusted to preference. A nonparametric Friedman's analysis of variance (ANOVA) test for seven related samples showed no significant difference among these three conditions ( $\chi^2 = 0.538, p > .05$ ). However, all three acoustic programs were found to be significantly more



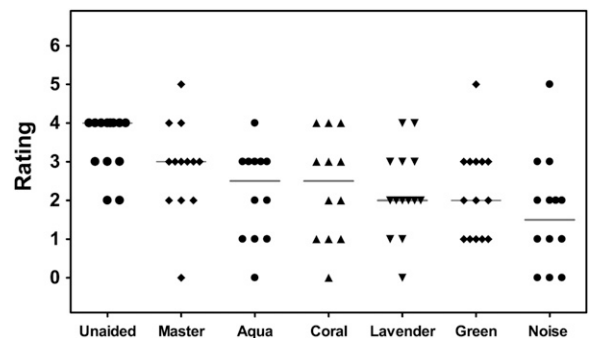
**Figure 3.** Relaxation ratings for three conditions following tuning to preference. Lower numbers indicate that the participant perceived the fractals as being more relaxing. The horizontal bars reflect the median ratings. 1 = very relaxing, 2 = somewhat relaxing, 3 = neither relaxing nor stressful, 4 = somewhat tensing, 5 = very tensing.

relaxing than neutral based on the nonparametric two-related-samples Wilcoxon signed-ranks test ( $p < .05$ ).

**Tinnitus Annoyance Scale**

The participants were asked to use the seven-point Tinnitus Annoyance Scale (0 is least annoying, 6 is most annoying) to rate their tinnitus annoyance for seven conditions (the four fractal settings, noise only, amplification "master" only, and no hearing aid). Annoyance was operationally defined as "any negative emotional reaction such as anxiety, irritation, frustration, anger, or displeasure" (Henry et al, 2004, p. 587). Note that these decisions were made during brief listening trials with each setting in the laboratory and do not reflect the 6 mo of actual wearing time.

The data shown in Figure 4 reflect differences among the ratings on seven acoustic conditions (unaided, master, aqua, coral, lavender, green, and noise only). The unaided condition has the highest median tinnitus annoyance rating, and noise only has the lowest median tinnitus annoyance rating. The four fractal settings had similar median annoyance ratings. The nonparametric Friedman's ANOVA test for seven related samples indicated that the acoustic condition had a significant effect ( $\chi^2 = 30.66, p < .001$ ). Post hoc analysis (Wilcoxon related-samples signed-rank test) comparing the unaided condition to other acoustic programs showed that the unaided condition had significantly more annoyance than the four fractal programs or the noise-only program ( $p < .05$ ) but was not different from the master ( $p > .05$ ). When noise alone was compared with the fractal programs, no significant difference was found ( $p > .05$ ). A nonparametric Mann-Whitney test indicated that hearing aid experience was not significant in determining the annoyance rating for each acoustic condition ( $p > .05$ ).



**Figure 4.** Tinnitus Annoyance Scale rankings during the initial listening trial in the laboratory. Most annoyance from tinnitus is at the top of the scale, and least annoyance is at the bottom. Horizontal bars reflect the median ratings. 0 = no annoyance, 1 = just slightly annoying, 2 = mildly annoying, 3 = moderately annoying, 4 = very annoying, 5 = extremely annoying, 6 = worst possible annoyance.

Although there were no significant differences in tinnitus annoyance among the four fractal settings, participants did show a preference for certain settings. Specifically, seven of the 14 participants preferred green, and five preferred aqua; lavender and coral were each preferred by one participant. A  $\chi^2$  test confirmed that the green setting was preferred more than coral or lavender ( $\chi^2 = 4.5, p < .05$ ). A comparison of lavender, coral, and aqua did not show significant differences.

### Tinnitus Annoyance Scale Rating at Self-Adjusted (Preferred) Setting

As explained in the Procedures section, participants were asked to select a preferred fractal program as well as make tempo and pitch fine-tuning adjustments for both the laboratory surveys and field trials. Figure 5 reflects the finding that, on average, participants tended to slow the tempo from the default setting and to a lesser degree tended to lower the pitch from their preferred default setting. Slowing the tempo agrees with the literature suggesting that slower beats tend to be more relaxing. Pitch selection seemed to be determined by personal preference and in some cases by audiometric configuration and was bimodal in distribution.

When comparing the four general test conditions (master, fractal + master, fractal + master + noise, and fractal alone) following self fine-tuning, a Wilcoxon signed-rank test with adjustment for multiple comparisons showed that the unaided condition had significantly more annoyance than the fractal + master and fractal + master + noise but was not significantly different from fractal only or master only ( $p < .05$ ). This is in agreement with the annoyance ratings that were made prior to the fine-tuning as well. These data are depicted in Figure 6. The adjusted ratings for some individuals showed differences but were not significantly better than the default rating for the group data.

Tinnitus Handicap Inventory and Tinnitus Reaction Questionnaire scores were obtained at four visits (ini-

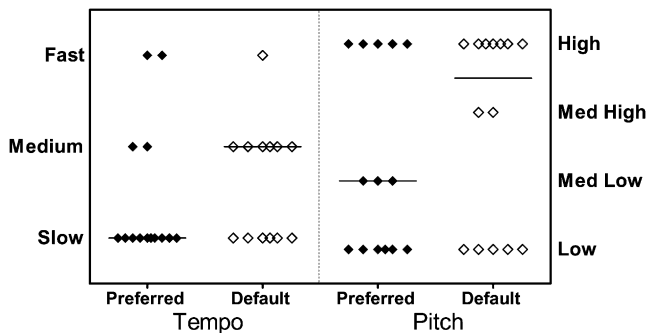


Figure 5. Ratings for preferred tempo and pitch versus default settings. Each symbol represents one participant.

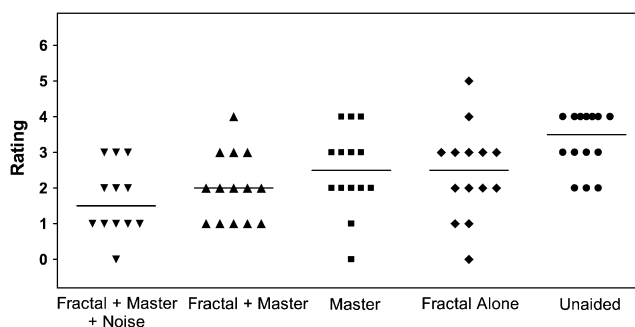


Figure 6. Comparison of acoustic conditions (with fractals adjusted to preference). 0 = no annoyance, 1 = just slightly annoying, 2 = mildly annoying, 3 = moderately annoying, 4 = very annoying, 5 = extremely annoying, 6 = worst possible annoyance.

tial, 1 mo, 3 mo, and 6 mo). Figure 7 reflects the progressive improvement in THI and TRQ scores over time. The mean THI score decreased (improved) from 58.7 to 42.0 after 6 mo. A repeated-measures ANOVA showed that visit was a significant factor ( $F[3, 39] = 4.31, p = .01$ , power of test = 0.8). Post hoc analysis using a paired-sample  $t$ -test showed that the initial visit had a significantly higher mean THI score than the 6 mo visit ( $p < .05$ ). The mean TRQ score decreased (improved) from 52.6 to 40.9 after 6 mo. Again, a repeated-measures ANOVA showed that visit was a significant factor ( $F[3, 39] = 4.07, p = .01$ , power of test = 0.8). Post hoc analysis with adjustment for multiple comparisons using a paired-samples  $t$ -test showed that the initial visit had a significantly higher TRQ than the 1 mo and 3 mo visits ( $p < .05$ ) but not the 6 mo visit ( $p > .05$ ). This is likely due to the reversals in scores at 6 mo for three of the participants. It should be noted that even though a post hoc analysis using a paired-samples  $t$ -test indicates that the only statistically significant change occurred within the first month, inspection of the raw data shows that the significant clinical change that occurred for four participants occurred between the first and third months and for one participant

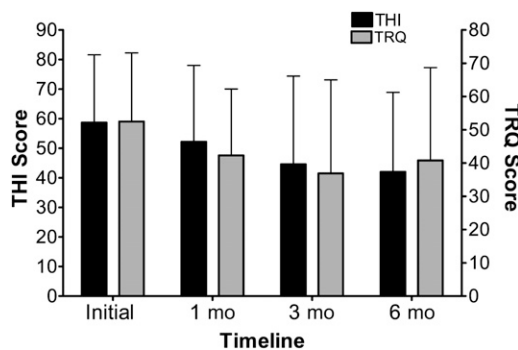
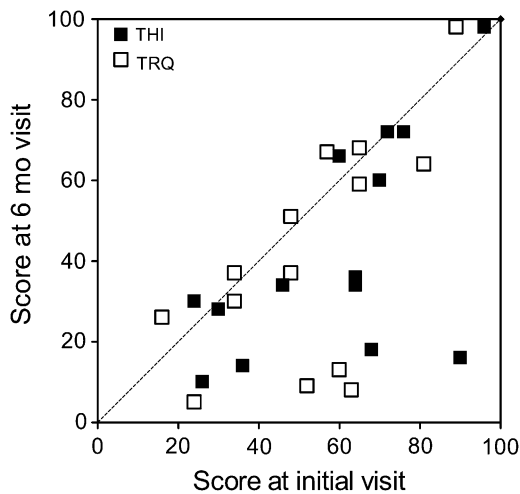


Figure 7. Mean Tinnitus Handicap Inventory (THI) and Tinnitus Reaction Questionnaire (TRQ) scores as a function of visit. Black bars represent THI, and gray bars represent TRQ.





**Figure 8.** Individual Tinnitus Handicap Inventory (THI) and Tinnitus Reaction Questionnaire (TRQ) scores from baseline and the end of the experiment. Each square represents a single participant’s performance. Filled squares reflect THI measures, and open squares reflect TRQ scores.

occurred twice (in the first month and again between the third and sixth months).

However, not every individual participant showed significant improvements. Because of the diverse reaction to tinnitus management approaches, we further examined individual responses, which are shown in the Figure 8 scatter plot. Each square represents a single participant’s performance. Filled squares reflect THI measures, and open squares reflect TRQ scores. Symbols plotted below the dashed line represent improvement over time. The THI considers a 20-point change to be clinically significant (Newman et al,

**Table 2. Raw Tinnitus Handicap Inventory (THI) Scores over Time**

Subject	Initial THI	1 Mo THI	3 Mo THI	6 Mo THI
<b>SG21</b>	90	92	<b>24</b>	<b>16</b>
JB22	24	18	26	30
JE23	46	44	32	34
SE24	96	96	96	98
YB27	70	66	58	60
<b>JM28</b>	68	<b>46</b>	52	<b>18</b>
CT29	76	76	98*	72
<b>DE31</b>	26	20	<b>6</b>	10
<b>JD32</b>	64	<b>38</b>	46	<b>36</b>
SG33	72	66	76	72
<b>DG34</b>	64	70	46	<b>34</b>
<b>CT38</b>	60	48	44	66
<b>PR41</b>	36	28	<b>6</b>	<b>14</b>
<b>SG44</b>	30	24	14	28

*Note:* Boldface indicates subjects showing a 20-point or greater difference from the initial baseline THI score.

\*Subject CT29 at 3 mo had been experiencing ill health prior to and during this visit.

**Table 3. Raw Tinnitus Reaction Questionnaire (TRQ) Scores over Time**

Subject	Initial TRQ	1 Mo TRQ	3 Mo TRQ	6 Mo TRQ
<b>SG21</b>	52	<b>32</b>	<b>13</b>	<b>9</b>
JB22	16	16	20	26
JE23	34	34	22	30
SE24	89	70	89	98
YB27	57	55	56	67
<b>JM28</b>	60	47	42	<b>13</b>
CT29	81	78	86*	64
<b>DE31</b>	24	22	<b>2</b>	<b>5</b>
<b>JD32</b>	65	40	43	59
SG33	65	62	66	68
<b>DG34</b>	63	58	<b>31</b>	<b>8</b>
<b>CT38</b>	48	39	<b>27</b>	51
<b>PR41</b>	48	<b>18</b>	<b>8</b>	37
<b>SG44</b>	34	21	<b>12</b>	37

*Note:* Boldface indicates subjects showing a 40% or greater difference from the initial baseline TRQ score.

\*Subject CT29 at 3 mo had been experiencing ill health prior to and during this visit.

1998). Using this criterion, six of the 14 participants obtained clinically significant improvements during the course of the study (though only five remained significant at the final visit).

As with the THI, there are variations in performance and improvements in the TRQ. The raw scores for each participant for both the THI and TRQ are shown in Tables 2 and 3. It should be noted here that the description of the TRQ does not offer the same guidelines for clinical significance (a change of 20 points or more) or severity classification as does the THI. In keeping with the TRQ analyses of other studies, a 40% change was chosen to denote clinical significance. This is consistent with the criteria selected by Davis et al (2007). This represents a conservative approach, in that other studies have used as little as a 20% (Hiller and Haerkotter, 2005) or a 30% criterion (Jastreboff, 1996; Nagler, 1998). Using the 40% criterion, there were seven participants who showed significant improvements during the study (though only four remained significant at the final visit).

**DISCUSSION**

**A** main objective of this investigation was to determine if tinnitus sufferers could benefit from the effects of fractal tones delivered through a wearable hearing aid. The study was not intended as a direct comparison to other tinnitus treatment procedures, nor was it designed to quantify the impact of wearable amplification in general since numerous studies have already confirmed the positive effect on tinnitus perception (Saltzman and Ersner, 1947; Surr et al, 1985, Trotter and Donaldson, 2008).

Laboratory-obtained data indicate that there was a range of preferences observed for fractal settings. The most preferred fractal programs were those that had a slow or medium tempo and a restricted dynamic range. This finding was also observed in a small group of nontinnitus hearing-impaired patients who were asked to rate the relaxation level of the fractal tones in the same manner as the tinnitus group. Thus, the preference trends for fractal settings do not appear to be specific to patients with tinnitus. Regardless of the sound qualities of the preferred fractal setting, most participants found the fractal settings to be relaxing.

The importance of allowing the participants to choose among various acoustic signals was apparent. While the anticipated expected musical preferences (i.e., most selected fractals with slower tempos) were chosen, the fact that there was no single preference among tinnitus participants underscores the benefit of providing the individual listener with choices. Individual preferences for certain types of acoustic stimuli were also emphasized in the Henry et al (2004) study in which they report that most, but not all, of their participants clearly preferred certain stimuli over others. Moreover, the current results agree with the Henry et al (2004) data in that their subjects showed a preference for stimuli that were modulated in both the spectral and temporal domains. This is characteristic of fractal and other musical stimuli. For example, the Henry et al subjects preferred stimuli with temporally varying characteristics (from the modulated DTM 6a CDs) over noise alone, as might be produced by a broadband noise generator. These factors may be part of the reason why noise masking has fallen out of favor among some practitioners as an acoustic tinnitus treatment. Although seven participants in the current investigation rated the noise-only condition as providing the least tinnitus annoyance (and noise alone produced the lowest mean tinnitus annoyance rating) in the laboratory, only two of the participants opted to have noise only as a program during the 6 mo of wearing the hearing aids, and none of them selected the noise-only condition as their preferred setting. Furthermore, while all four of the experienced hearing aid users selected noise as producing the least annoying tinnitus in the laboratory, only one selected it for field wear. Thus, it is possible that noise was associated with the lowest tinnitus annoyance in the time-limited laboratory condition because of its masking effect (ergo the reduction in tinnitus annoyance), but this acoustic signal was not deemed desirable or viable in the real world. It is also interesting to note that participants were more likely to select noise as a program when it was embedded in the fractal + master setting.

Similarly, though the lavender setting was rated the least relaxing, it, along with the green and the noise-only conditions, created the least tinnitus annoyance. Again, this may be related to the possibility that it produced

the most masking (likely because the tempo was fast and the duration between tones was thus shorter), however, for either the short term or long term, participants did not find this fast-tempo signal relaxing and therefore did not choose to listen to it during the 6 mo trial.

The majority of the Henry et al (2004) subjects also preferred the amplitude-modulated DTM 6a CDs sounds over the seven Moses/Lang filtered white noise sounds even though the latter stimuli contained several tracks extending to 14 kHz. Thus, the bandwidth limitations of current hearing aids may not pose a critical restriction. Moreover, there is a significant advantage to being able to deliver the fractal stimuli via a wearable device that also provides amplification. And of course, the hearing deficit can be compensated for by applying the algorithm of the hearing aids to the fractal tones, a potential advantage over prerecorded stimuli such as the DTM 6a CDs.

Minimizing the dynamic range is reported by Hann et al (2008) as being important, and this may be a key musical selection criterion. It makes sense that tinnitus patients do not wish to be participant to unexpected sudden increases in amplitude. Pitch seemed to be less important (or more subject to personal preference), in that the most preferred setting, green, had a higher pitch with reverberation, while the second most preferred setting, aqua, had the lowest default pitch. It should be noted, however, the many participants used the fine-tuning feature to alter the default pitch of the green setting to a lower pitch. The other common feature of the two preferred fractal settings was the tonality. Both the green and aqua settings utilize major keys. This is the same finding reported by Hann et al (2008). Their subjects compared four well-known baroque musical passages: Bach's Air in G (which, parenthetically, is also one of the tunes present in other tinnitus treatment protocols), Albinoni's Adagio, and two of Vivaldi's Four Seasons. Their conclusion is that the major mode is the common musical element for preference. This is consistent with the elements of music most associated with a positive emotional response (Hevner, 1933; Bella et al, 2001). Lavender, the least preferred fractal setting, also used a major key; however, the fact that it has the fastest tempo may have been the overriding factor accounting for its lack of preference. Only three (15%) of the participants preferred the fastest tempo, with 11 participants preferring the slowest tempo (60%). These findings also agree with the literature on general musical preferences showing that slower tempos are most relaxing and preferred. Thus, notwithstanding the fact that fractal music differs from conventional music in terms of its familiarity, similar preferences appear to apply.

Participants were instructed to wear the fractal setting for a "relaxation session" that lasted at least 15 min

a day. At all other times the participant could select the preferred listening setting, although the participants were asked to try different listening programs during several everyday activities and to document the preferred listening program. Participants listened to the fractal tones for an average of 2 hr more per day than was required by the study protocol. This implies that participants did perceive benefit from the fractal tones in everyday listening environments.

Participants were assessed before, during, and at the conclusion of a 6 mo trial with hearing aids containing fractal tones and noise as program options, which have become commercially available since the end of this study. Thirteen of 14 participants reported that their tinnitus annoyance was reduced for at least one of the amplified conditions (with or without fractal tones or noise) relative to the unaided condition. As stated earlier, this is consistent with the literature reporting beneficial effects from amplification, possibly due to the increased stimulation producing a decrease in central nervous system gain (Saltzman and Ersner, 1947; Surr et al, 1985). In addition, nine subjects assigned a lower tinnitus annoyance rating when listening to fractal tones alone versus the amplification-alone condition. THI or TRQ scores obtained during and after the field trial were significantly reduced in about half of the tinnitus participants. These particular participants reported highly significant improvements on at least two of the three domains measured.

There is an inherent danger in considering only group data when investigating options for tinnitus patient management. Despite the fact that only about half of the participants displayed statistically significant changes on the THI or TRQ, eight of them chose to pursue amplification with fractal tones at the conclusion of the project. The fact that subjects were given the option to purchase amplification at a reduced price for their participation in the study and yet eight chose the devices containing fractal tones implies a perceived value to the fractal option. In fact, when asked at the final visit if having additional sounds increased their overall satisfaction with amplification, 11 of the 14 (78%) replied positively.

Because tinnitus participants are diverse, it was helpful to analyze the participants individually, as no single treatment has been determined to be a panacea for tinnitus, and domains other than tinnitus handicap, reaction, and annoyance may influence a participant's perception of tinnitus. One severely affected participant (SE24) who did not show improvements on the TRQ and THI measures scored near the maximum for all annoyance, reaction, and handicap measures at every visit, yet he reported one of the most dramatic and positive responses to the fractal tones generated by the hearing aids and subsequently opted to obtain amplification with fractal tone options at the conclusion of the study.

This supports the notion that domains other than handicap and reaction, such as listening ease or listening effort, led these participants to prefer the experimental hearing aids. For most tinnitus participants, amplification alone provided a reduction in tinnitus annoyance versus no amplification, which is in agreement with other studies (Saltzman and Ersner, 1947; Surr et al, 1985; Trotter and Donaldson, 2008). Likewise, for 12 of the 14 tinnitus participants, the tinnitus annoyance rating was lower when listening to at least one of the amplified fractal conditions than for the unaided condition. In addition, nine participants assigned a lower tinnitus annoyance rating when listening to the fractal tones alone versus the amplification-alone condition. However, for long-term usage, as demonstrated by the data log over the course of the 6 mo study, participants chose to use amplification alone (the master program) on average 60% of the time, while amplification plus a combination of fractals and/or noise was worn 30% of the time, and fractal alone was used 10% of the time. The implication is that while minimizing the annoyance of tinnitus is important, the ability to hear better is deemed at least as important. This is an interesting finding considering the fact that prior to the study only four of the 14 tinnitus participants wore hearing aids.

THI and TRQ scores improved over the course of the 6 mo trial, with clinically significant improvements occurring for over half of the participants on at least one of the measures. Since all participants received similar counseling at least 3 mo prior to entering the study, it can be argued that differences in performance and preference were not primarily a function of counseling. It cannot, however, be claimed that the specific devices used in this experiment alone were responsible for the demonstrated benefits since it is not possible to definitively rule out spontaneous changes, a placebo effect, or the impact of any type of amplification. Furthermore, it is not possible to accurately assign benefits due to the fractal tones versus the benefits provided by the amplification. This is because a limitation of this study was a lack of a control group during the 6 mo field study. However, since our purpose was not to determine whether amplification would be useful (that had already been proven in numerous studies) but, rather, to ascertain if the addition of the fractals might be desirable and beneficial, the main conclusions reached below are not compromised.

If fractal signals helped certain participants reduce tinnitus annoyance, handicap, and negative reaction, one might anticipate that these signals were also relaxing. When asked about the effect of each of the programs containing fractals, 70% of the participants judged the programs as being relaxing or slightly relaxing, while 20% judged them as neutral, and only 10% deemed them slightly tensing. There was an approximately

even spread among fractal alone, fractal + master + noise, and fractal + master. Again, however, participants had definite opinions and preferences for certain programs and for certain fractal characteristics. The vast majority (86%) of the participants indicated that it was easier for them to relax while listening to the fractal signals.

## CONCLUSIONS

The purposes of this experiment were to determine if the presence of various acoustic stimuli, including fractal tones, delivered through a hearing aid would (1) provide a relaxing listening background to hearing-impaired participants suffering from tinnitus and (2) reduce short-term tinnitus annoyance. The data indicate that this was the case for the vast majority of participants. A third objective was to determine whether the addition of fractal tones to a wearable hearing aid would lower the subjective tinnitus handicap and reaction ratings. The data indicate that about half of the subjects reported decreased scores on the subjective scales; however, it is not possible to delineate the relative contribution of the fractal tones versus the overall effect of amplification. The subject population was felt to be a particularly difficult one, in that they had a less-than-average response to counseling. Therefore, further research should be conducted in order to determine whether the current findings generalize to the larger tinnitus population.

Similar to most tinnitus studies, the results suggest a wide range of responses to treatment options. This may reflect the wide range of etiologies that cause tinnitus as well as the significantly varied emotional responses to tinnitus experienced by patients. As correctly stated by Henry et al (2004), extending options to tinnitus sufferers is essential. While not a panacea or a universally accepted stimulus, fractal tones do provide another acoustic option. A decade ago it was believed that only a small proportion—approximately one-quarter—of tinnitus sufferers were obvious candidates for amplification (Jastreboff, 2000). Now, however, the increased use of open-fit postauricular hearing aids is allowing for a broader range of patients with milder degrees of hearing loss to be successful hearing aid users. This can benefit tinnitus sufferers who previously were not interested in amplification. Moreover, the ability to take advantage of individual listening preferences allows a variety of acoustic signals including familiar music, unfamiliar fractal tones, and noise to mix with amplification. This study showed that some, though not all, tinnitus sufferers can, and will, take advantage of amplification devices that can both promote tinnitus management and provide quality hearing. While there was no indication from this investigation that would help ascertain which participants will likely benefit

from and enjoy fractal signals, it was found that those who do will show strong preferences for this feature.

It is important to stress, however, that acoustic treatments of tinnitus alone will likely not suffice. The most common tinnitus treatment procedures currently in use understandably employ a combination of counseling to address negative associations in the limbic system and some form of acoustic therapy to produce a reduction in central nervous system gain by stimulating auditory structures including the dorsal cochlear nucleus and auditory cortex, to reduce the contrast between tinnitus and silence, and to further stimulate the parasympathetic nervous system, thus promoting a less negative emotional response.

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