

Effect of Counseling, Amplification and Fractal Tones in Tinnitus Management

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Abstract

Introduction: Educational counseling, sound stimulation and stress reduction have been shown to be effective in reducing tinnitus distress. Hearing aids that include a sound generator capable of producing relaxing fractal tones and amplification seem to be an ideal solution for managing tinnitus patients. This study aimed to investigate the effectiveness of counseling, amplification and fractal tones applied sequentially.

Method: 35 subjects with hearing loss and Tinnitus Handicap Inventory (THI) scores >18 participated in the study. Their mean age was 57 (± 8) years. The tinnitus management had three phases: educational counseling, amplification and sound stimulation by use of fractal tones. Each phase lasted two months on average. The intervention period was six months. Most subjects initially reported tinnitus to have a moderate to severe negative impact on their quality of life. Subjects were instructed to use the hearing aids several hours per day and listen to the fractal tones for a minimum of two hours per day. THI questionnaires were applied at baseline, after each phase of the protocol (i.e., counseling, amplification and sound stimulation) and 12 months post-treatment. Additional questionnaires regarding hearing aid and sound stimulation experiences were also collected.

Results: The majority of subjects showed a clinically and statistically significant reduction in perceived tinnitus-related distress after six months and 12 months post-treatment ($p < 0.001$). Improvements were seen after counseling ($p < 0.001$), and after hearing aids and sound stimulation ($p < 0.003$). The vast majority of subjects were very satisfied with the hearing aids and evaluated the sound stimulation as being either satisfactory or very satisfactory. The average use of the hearing aids was 9 hours a day.

Conclusion: Overall the findings show that a combined approach with counseling and hearing aids that include a sound generator capable of producing fractal tones is a successful tool in tinnitus management.

Keywords: Tinnitus; Directive counseling; Amplification; Fractal tones; Relaxation

Introduction

Tinnitus represents one of the most common and distressing otologic problems. It is most clearly associated with noise exposure and aging and can present with comorbid sleep disturbance, hearing difficulty, social withdrawal, and negative emotional reactions such as anxiety and depression [1,2]. The role of psychosomatics and stress reactions in the development of tinnitus is corroborated by the neurophysiological model proposed by Jastreboff and Hazell [3]. Tinnitus affects 10 to 15% of adults [4], but it is considered moderate to severely annoying in about 5% of the population [5].

There are no cures available for chronic tinnitus [6]. Consequently, the majority of treatment options are directed primarily toward reducing or managing the accompanying symptoms associated with tinnitus [7].

Traditional approaches to tinnitus management typically combine education and counseling, stress reduction, relaxation and use of therapeutic sounds [8] to reduce the tinnitus distress and improve the Health Related Quality of Life (HRQoL).

Directive counseling has been considered effective in tinnitus management [9]. Clinically significant changes in tinnitus measures after directive counseling have been reported over no intervention or undirected self-help [10-12].

Sound enrichment is offered in many tinnitus management programs, whether the intention is to make tinnitus less noticeable, provide immediate relief, promote control, promote habituation, provide a distraction of attention, or promote plastic change in the central auditory system [6]. However it is speculated that the favorable results obtained with sound therapy treatment may be mediated from the counseling and not necessarily from the acoustic stimulation itself [13].

Hearing aids are a current mainstay of the audiological management of tinnitus [14-17] because hearing loss is the main risk factor for tinnitus [18]. It is uncertain, how much of the benefit results from a change in reactions to tinnitus and how much to an improvement in hearing function [19]. Other forms of sound therapy have been applied to tinnitus management such as sound generators [20,21] and Neuromonics Tinnitus Treatment - NTT [22-24].

Recently combination devices that consist of hearing aids with either noise generators or some kind of music [25] have been used in tinnitus management. Music is believed to be helpful in reducing stress because of the wide range of neural structures that are activated during

music appreciation. This includes the cerebellum, frontal lobe, limbic system, and auditory cortex [26]. The use of music has been shown in numerous studies to reduce the stress of patients in clinical settings [27-29]. Hearing aids with fractal tones have also been used in tinnitus management [19,30,31]. The fractal tones are semi-randomly generated tones that sound like wind chimes. Predictable without being monotonous, they sound familiar, but are not associated directly with music that the listener can remember [32]. Fractal tones are pleasant and have been proposed to promote relaxation, which might in turn have some benefits for persons with tinnitus. The fractal tones are available as a hearing aid program (Wide Zen program) in most Widex hearing aids. The hearing aids have the option to include programs that provide amplification alone, Zen with the microphone amplification turned on or off [30]. There are six Zen styles available - five different fractal tones that differ in pitch and tempo, and Zen noise. Aqua style is the most preferred Zen tone pattern [33] and is also the default recommendation.

A number of studies have supported the use of fractal tones in hearing aids in tinnitus management. Kuk et al. [31] reported a survey of patients who have been fitted with fractal hearing aids by clinicians with some training in tinnitus management where 69% of patients had Tinnitus Reaction Questionnaire (TRQ) improvements greater than 20 points. Sweetow and Sabes [26] monitored changes in the Tinnitus Inventory Handicap (THI) questionnaire and TRQ over a six month period following the fitting of fractal tones in the hearing aids to 14 subjects. 36% of the subjects had THI improvement over 20 points and 29% had a 40% or greater improvement in TRQ. Herzfeld and Kuk [33] also reported that the fractal tones were effective sound therapy tool in tinnitus management. 48 subjects with tinnitus were fitted with fractal tone combination hearing aids and followed regularly for a year. The average improvement in TRQ scores (as well as tinnitus rating and tinnitus disturbance rating) was around 60% for all measures. Recently, Herzfeld et al. [34] also reported significant improvements in tinnitus related distress when Widex Zen Therapy was applied. 74% and 75% of subjects achieved clinically significant changes in their THI and TFI scores, respectively at the end of the six months evaluation interval. Fractal hearing aids associated with directive counseling seem to be an effective tool for tinnitus management.

A range of studies have been conducted on the effectiveness of counseling, amplification and fractal tones but no clinical study has investigated the isolated effect of each of the three components in a sequential tinnitus management program. This study investigated the effectiveness of directive counseling, amplification and sound stimulation with fractal-based musical chimes on tinnitus severity, applied sequentially across subjects with significant tinnitus distress and hearing loss over a period of six months and 12 months. Additionally, this study aimed to investigate the effects of the fractal tones in inducing relaxation and reducing tinnitus distress.

Method

Clinical site

The data collection was done at the Center for Hearing Devices and Communication (CHK) in Denmark. CHK is a public center that provides free hearing aids, combination devices or sound generators associated with counseling to patients with significant tinnitus distress.

Participants

40 subjects with clinically significant tinnitus (THI>20) and hearing loss were included initially in the study. Five subjects were removed from the study. Two subjects were excluded because their THI at baseline were lost. Three subjects were removed due to severe psychological problems. All subjects had undergone a recent ENT evaluation to rule out medical treatment for their tinnitus. All participants had cognitive and manual dexterity abilities sufficient to undergo treatment. The subjects were informed about the study purpose and the phases of treatment and they signed a consent form. The mean age of the participants was 57 (± 8.7) years. 25 subjects were male and 10 were female. 28 subjects (80%) were first time hearing aid users. The mean hearing thresholds are shown in the Figure 1.

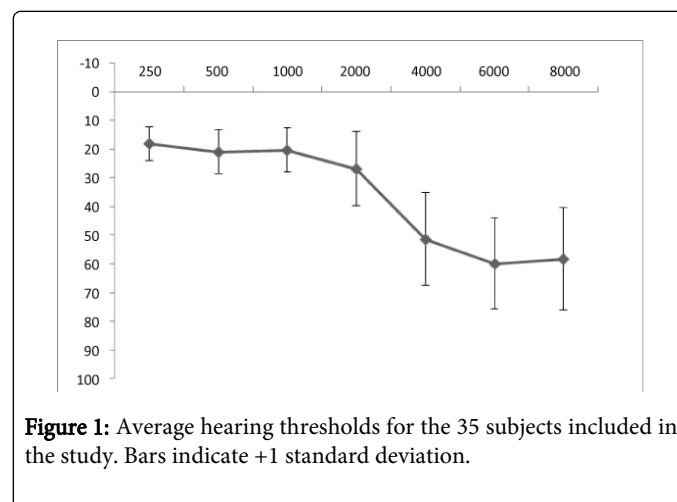


Figure 1: Average hearing thresholds for the 35 subjects included in the study. Bars indicate +1 standard deviation.

Procedure

All subjects included in the study underwent (1) an assessment appointment, (2) an instructional counseling appointment, (3) hearing aid fitting appointment (two months post-counseling), (4) activation of fractal tones in the hearing aids-“Zen program” (two months post-HA fit) and (5) a final appointment (two months post-Zen fitting).

Assessment session: The ENT and audiological evaluation was carried out outside of CHK. The subjects were then referred to CHK for tinnitus management. The assessment appointment was carried out by an audiologist specialized in tinnitus management and included the collection of Tinnitus Handicap Inventory (THI), CHK Tinnitus questionnaire and review of the evaluation and recommendations for the treatment.

Instructional counseling session: The directive counseling was given by an audiologist with experience in tinnitus counseling. The staff at CHK used a structured client form and the counseling session varied from 1-1.5 hours. The topics included an overview of the auditory system, tinnitus and hearing loss, causes of tinnitus, tinnitus characterization, strategies for tinnitus management, including technical solutions and hyperacusis. An extra counseling session was arranged for only three patients. Approximately one third of the subjects received a bed-side masker due to sleep problems. At the end of the counseling sessions, patients were told to return in 8 weeks for the hearing aid fitting.

Hearing aid fitting session: The second THI was collected two months post-counseling just prior to the hearing aid fitting. All

subjects were fitted bilaterally with Widex Clear440 passion models with instant ear tips. Ninety percent of the fittings were open fittings. This is a 15 channel enhanced dynamic range compression hearing aid with a compression threshold as low as 0 dB HL. Among the features are noise reduction, active feedback cancellation and data logging. Additionally, the subjects used a remote control to adjust volume and to change hearing aid programs. The hearing aid fitting was done by an audiologist experienced with Widex hearing aids and Zen programs. Fine-tuning of the hearing aid was done when necessary.

Fractal tones session: The third THI was collected two months post-amplification together with the hearing aid questionnaire. Subjects were given two Zen programs during the Zen fitting visit: (1) Aqua style with microphone on and (2) Aqua style with microphone off. The subjects were instructed to listen to Zen programs a minimum of two hours per day and they could choose between Aqua with Microphone on or off, whatever Zen program would be most adequate for them. Master (amplification only) was recommended for listening situations where hearing and communication were essential. A fine-tuning appointment was done if it was necessary.

Final session: The fourth THI form was collected two months post-fractal tones together with Zen questionnaire. The usage of the hearing aid was assessed through the data logs. Subjects were told that they would be contacted 12 months after the treatment finished.

Measurement instruments

The Tinnitus Handicap Inventory (THI) was administered as the principal measurement instrument in the study. It was chosen because of its well-established and robust psychometric properties, including test-retest reliability, construct validity, and internal consistency [35]. THI was collected at baseline, two months post-counseling, two months post-hearing aid fitting, two months post-Zen program (end of treatment) and 12 months post-treatment, where THI forms were sent to the participants. 31 of the 35 subjects returned the 12-months post treatment THI questionnaire.

Additionally, a hearing aid and a Zen questionnaire were administered to investigate the overall satisfaction with the hearing aids and the relaxation effects of Zen. The use time for the Master (main program) and fractal tones programs was assessed in the final session.

Data analysis

Descriptive statistics were used for all outcomes, and a non-parametric repeated measures Friedman's ANOVA was applied to measure changes in the THI during and after the treatment protocol. Post hoc analysis with Wilcoxon related-samples signed rank test was applied to compare the effects of different treatment phases (counseling, amplification and sound therapy with fractal tones). Descriptive statistics were compiled on Excel 2010. Inferential analyses were conducted with SPSS software Version 20.

Results

THI (Tinnitus Handicap Inventory)

The mean THI scores are shown in Figure 2. Subjects experienced statistically significant improvements in THI scores from baseline at two months post-counseling, two months post-amplification, two months post-fractal tones and 12 months post-whole treatment

(Friedman's ANOVA ($X^2=37,48$, $p<0.001$)). Post-hoc analysis (Wilcoxon related-samples signed rank test) comparing the treatment phases show statistically significant improvements post-counseling ($p<0.001$); post-Zen fit ($p<0.01$), and Post HA+Zen (sound therapy) ($p<0.003$). No statistically significant improvement was seen post-hearing aid fitting.

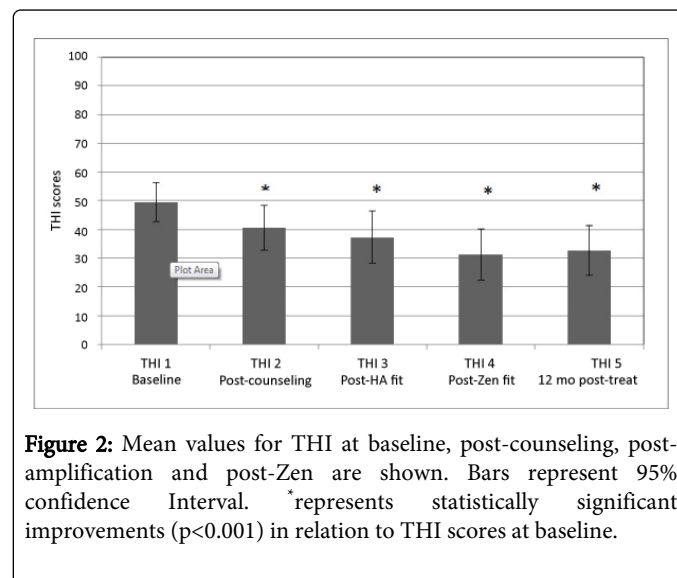


Figure 2: Mean values for THI at baseline, post-counseling, post-amplification and post-Zen are shown. Bars represent 95% confidence Interval. *represents statistically significant improvements ($p<0.001$) in relation to THI scores at baseline.

Individual THI scores between six months and baseline are displayed in the scatter plot shown in Figure 3A. Each point represents a single participant's performance. Additionally, individual outcomes between baseline and post-counseling; post-counseling and post-amplification and post-amplification and post-Zen fitting are also displayed in Figure 3B, C and D respectively. The solid diagonal line reflects identical pre and post scores (i.e., zero difference score). Any points falling below this diagonal suggests a reduction in tinnitus handicap. Any point above this line indicates a worsening of tinnitus handicap. Most subjects (85.7%) had shown tinnitus reduction at the end of the treatment. The dashed line represents the 20 point criterion that indicates a clinically significant reduction in THI scores and an improvement of quality of life [35]. Inspection of individual data revealed that fifty one percent (18 subjects) had a clinically significant reduction on THI scores after six months. The scatter plots in Figures 3B, C and D allowed one to estimate the efficacy of each treatment component in a two months period. Figure 3B shows that eight subjects (22%) showed >20 points improvement after counseling. Figure 3C showed that an additional 5 (14%) subjects showed >20 points improvement after hearing aids fitting. Figure 3D showed that an additional six subjects (17%) showed 20 points improvement with the use of the fractal tones.

Hearing aids and Zen questionnaires

All subjects reported being satisfied and very satisfied with the hearing aids after two months of hearing aid use (amplification). Data on subjects' overall satisfaction are shown on Figure 4A and B.

One of the main questions of this clinical study was to investigate whether fractal tones would help to reduce tinnitus distress and how fractal tones were used by subjects. The majority of subjects listened to the Zen program once a day and some up several times per day. Most subjects (87%) preferred to use Zen with the microphone on for more than two hours per day (Figure 5A and B).

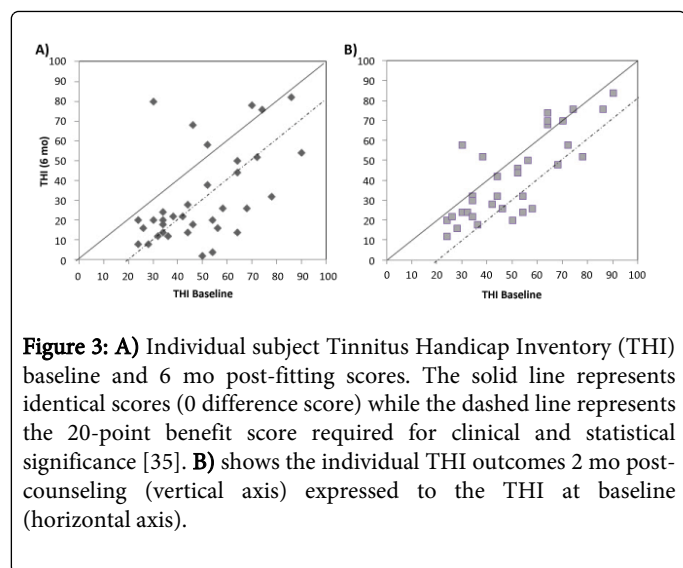
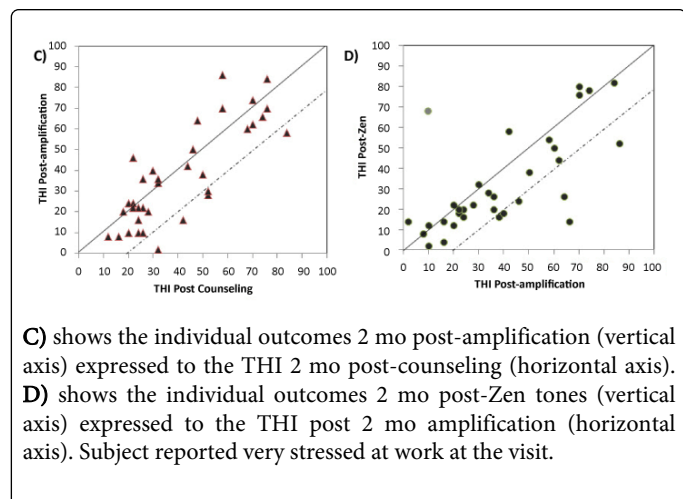


Figure 3: A) Individual subject Tinnitus Handicap Inventory (THI) baseline and 6 mo post-fitting scores. The solid line represents identical scores (0 difference score) while the dashed line represents the 20-point benefit score required for clinical and statistical significance [35]. **B)** shows the individual THI outcomes 2 mo post-counseling (vertical axis) expressed to the THI at baseline (horizontal axis).



C) shows the individual outcomes 2 mo post-amplification (vertical axis) expressed to the THI 2 mo post-counseling (horizontal axis). **D)** shows the individual outcomes 2 mo post-Zen tones (vertical axis) expressed to the THI post 2 mo amplification (horizontal axis). Subject reported very stressed at work at the visit.

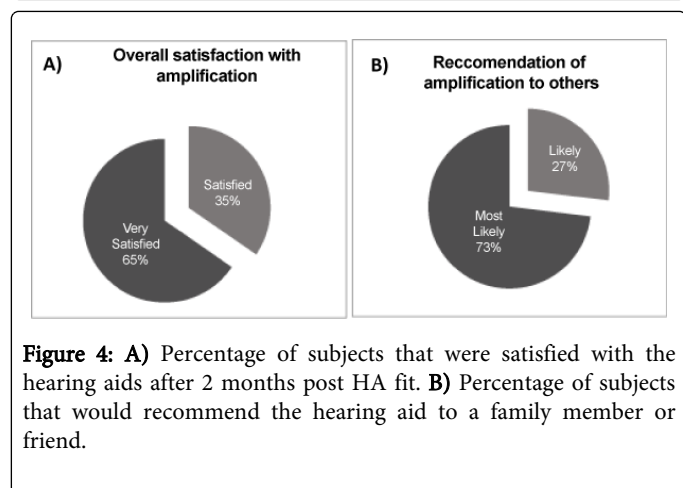


Figure 4: A) Percentage of subjects that were satisfied with the hearing aids after 2 months post HA fit. **B)** Percentage of subjects that would recommend the hearing aid to a family member or friend.

The effects of fractal tones on inducing relaxation, reducing tinnitus distress, tinnitus awareness and tinnitus annoyance are shown in Figure 6. The majority of subjects (70%) reported a good/very good relaxation effect with Zen. About 50% of the subjects reported good/very good effect in reducing stress. The majority of subjects (63%) reported that Zen had good/very good effect in reducing tinnitus

awareness and finally, fifty two percent (52%) experienced that Zen helped reduced tinnitus annoyance. Less than 10% of subjects reported fractal tones had a poor/very poor effect on tinnitus.

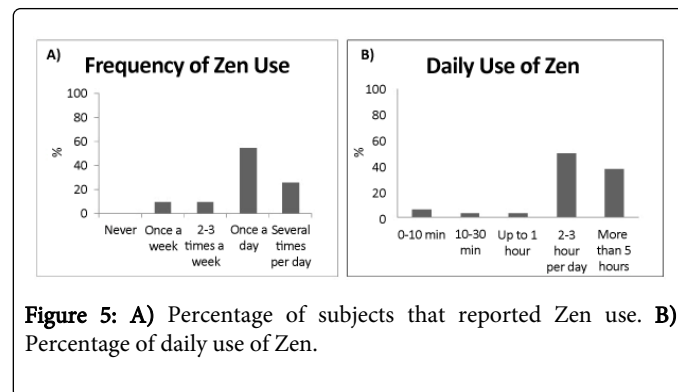


Figure 5: A) Percentage of subjects that reported Zen use. **B)** Percentage of daily use of Zen.

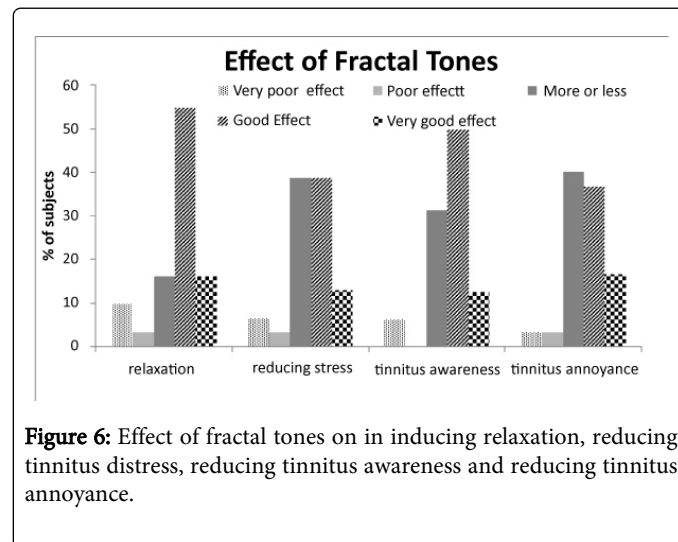


Figure 6: Effect of fractal tones on in inducing relaxation, reducing tinnitus distress, reducing tinnitus awareness and reducing tinnitus annoyance.

Overall, the majority of subjects (90%) would recommend the Zen program to a family member or friend. 75% were satisfied/very satisfied with Zen program. The percentage of subjects that were very unsatisfied/unsatisfied was below 10% (Figure 7A and B). Sixty four percent of subjects reported continued use of Zen (fractal tones with MIC ON or OFF) at the end of the 12 month treatment.

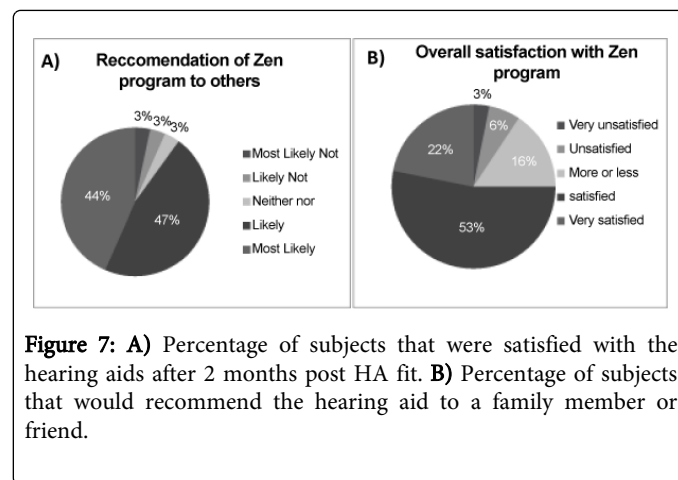


Figure 7: A) Percentage of subjects that were satisfied with the hearing aids after 2 months post HA fit. **B)** Percentage of subjects that would recommend the hearing aid to a family member or friend.

Device use

Data log: The data log of the hearing aids was accessed at the final visit. The mean use of hearing aids was 8.8 hours (± 3.9). On average Zen with MIC ON was used for two hours while Zen with MIC OFF was used for 40 minutes. No correlation was found between the use of hearing aids, Zen and improvement on the THI ($p > 0.05$). However, most subjects who reported Zen to have a good/very good relaxing effect on tinnitus listened to the Zen program between two and five hours per day (Figure 8A and B).

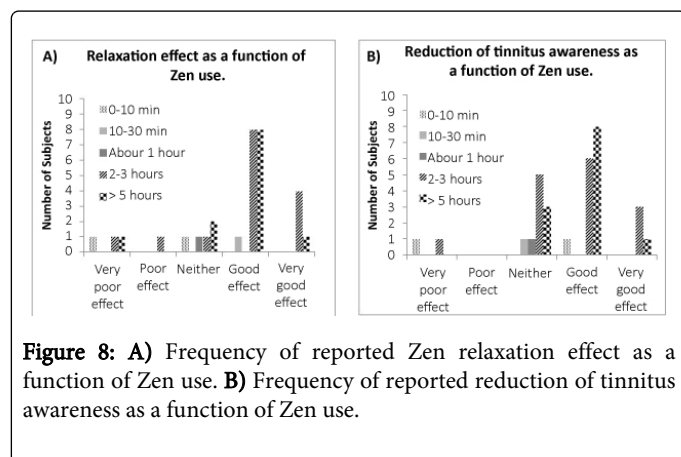


Figure 8: A) Frequency of reported Zen relaxation effect as a function of Zen use. B) Frequency of reported reduction of tinnitus awareness as a function of Zen use.

Discussion

The effectiveness of overall treatment protocol

The aim of this study was to investigate the cumulative effect of three tinnitus management approaches, i.e., counseling, amplification and fractal tones over a six months treatment and especially the effectiveness of each approach in reducing tinnitus related-distress over a two months-period. The final THI scores (six months post-treatment) had a significant reduction of 18 points. The mean THI scores was 49 at baseline and 31 post-treatment, indicating the subjects have moved from moderate to mild category. From a clinical perspective, it was observed an improvement in HRQoL of these subjects [35]. According to Newman et al. [35], a change in the total THI score of at least 20 points suggests that treatment is statistically and clinically effective. Fifty one percent of subjects ($N=18$) showed greater reduction ($\text{THI} \geq 20$) in the THI scores after six months of treatment. More recently, Zeman et al. [36] recommended a 7 point difference to represent the minimum difference to be clinically significant, based on a sample of 210 patients with a calculated effect size of $d=0.5$ (medium effect).

Sound therapy through masking and tinnitus retraining therapy/habituation approaches have been reported to significantly reduce tinnitus distress [20,21,37,38]. However, such approaches often take a longer time period (such as 18 months) to achieve its intended effect. Significant improvements in tinnitus symptoms have been reported in less than six months for patients with Neuromonics [23,39-44]; Widex Zen [30,33] and Widex Zen Therapy [34]. The current approach achieved also significant improvements in a short period of time.

The magnitude of improvement on THI after six months of sound therapy was dependent on the patient's initial THI score. The patients categorized as having at least a moderate degree of tinnitus handicap demonstrated greater reduction in THI scores in comparison to those

patients with minimal to mild THI scores. These observations are similar to those reported previously [7,21].

No significant difference was found between the THI at the end of treatment and 12 months after treatment. The 12 month THI scores show that the improvements obtained at the end of the treatment were maintained over time with a slight increase of 1.4 points in the mean THI scores, indicating a long-term treatment benefit with this combined approach.

Effects of counseling, amplification and fractal tones

A gradual improvement in the mean THI scores was seen post-counseling, amplification and fractal tones for 80% of the subjects, indicating a cumulative effect of the three management approaches during the six months treatment. Closer inspection of the data on the efficacy of each approach in reducing tinnitus distress ($\text{THI scores} \geq 20$) reveals that eight subjects (22%) showed improvements after counseling, and an additional 5 (14%) subjects after hearing aids fitting and six (17%) after the fractal tones. Directive counseling has been reported as an effective approach in tinnitus management [10-12]. These results indicate that sound stimulation or sound enrichment provided by a combination device can further enhance the treatment benefits, especially because the subjects also had a hearing loss [17].

Post-hoc analysis revealed no significant changes in THI scores after two months of the hearing aid fitting. This is quite interesting, since most subjects had a moderately sloping hearing loss and were first time HA users. From this it can be interpreted that tinnitus distress was the main reason that subjects searched for treatment at CHK and not the hearing loss itself. Even though no significant reduction was found in THI scores, all subjects reported that they were satisfied/very satisfied with the amplification and wore the hearing aids even after two months of hearing aid fitting (Figure 4A and B). Five subjects (14%) had a clinically significant reduction (≥ 20) on THI after amplification; however the significant changes in THI scores were not correlated to the severity of hearing loss. Perhaps amplification by hearing aids helped refocus attention on sounds that are different from the tinnitus sound or improving communication [14,45,46]. Six subjects had obtained significant improvements ($\text{THI scores} \geq 20$) after the fitting of fractal tones. Since the fractal tones were the last component provided to the subjects, the ones that improved more than 20 points still had high THI scores after counseling and amplification.

The current study applied each of the three tinnitus treatment components in a sequential order. One may wonder if the use of fractal hearing aids combined with counseling simultaneously would be even more effective in reducing tinnitus distress. Interestingly, higher rates of improvements are reported when counseling and fractal hearing aids are given together. Kuk et al. [30] reported a survey of patients that had been fitted with the fractal hearing aids by clinicians with some training in tinnitus management. 18 (69%) of 26 participants, who completed the TRQ questionnaire both pre-and post-fitting, had TRQ improvements of greater than 20 points. Herzfeld and Kuk [33], reported that 90% of patients ($N=45$) achieved greater than 40% improvement on TRQ scores. More recently, Herzfeld et al. [34] reported a success rate of 74% in six months through the use of the Widex Zen Therapy, an individual approach that combines amplification, fractal tones, instructional counseling, relaxation exercises and cognitive behavioral intervention. The simultaneous combination of different components according to the

specific needs of the patients may further increase the success rate of a tinnitus management program [32].

Effect of fractal tones

The effect of fractal tones in inducing relaxation and reducing stress and other symptoms related to tinnitus was further investigated in this clinical study. The percentage of subjects who reported good/very good effect of fractal tones on relaxation, stress reduction, tinnitus awareness and tinnitus annoyance varied between 50 and 70%. This may indicate that Zen can be used as a relaxation tool, helping to reduce tinnitus awareness and tinnitus annoyance. 70% of subjects reported good/very good relaxation effect after the use of fractal tones. This finding is in agreement with Sweetow and Sabes [26], who reported that 70% of their subjects considered fractal tones to be relaxing. Considering that the fractal tones are based on the hypothesis that bothersome tinnitus involves limbic system activity where tinnitus is associated with a stress response, and that music has de-stressing properties [31], fractal tones seem to be a plausible solution for most subjects. Fractal tones combined with amplification may facilitate passive listening which capitalizes on the ability of the brain to habituate to a non-salient, nonthreatening stimulus when the subjects can wear the device during their waking hours. The majority of subjects (75%) reported that they were satisfied/very satisfied with fractal tones at the end of the trial (two months after Zen fitting). It is not clear from the study results that there is a strong correlation between the relaxation effects obtained by use of fractal tones and reductions in tinnitus distress (i.e., THI difference between post HA fit and post Zen). The average use of fractal tones was two hours per day (25%), while the amplification use was six hours (75%). However, the subjects that reported good/very good relaxation effect of fractal tones had listened to the fractal tones between two to five hours per day.

We acknowledge that there are several limitations with this study. This is a cohort study where the effects of three approaches are investigated sequentially. Two months may be too short a period to evaluate the efficacy of each treatment approach. Future studies comparing noise and fractal tones would be desirable to investigate if fractal tones are more effective than noise in reducing the tinnitus distress. Moreover, future studies that incorporate neurophysiological measures of limbic system activity to quantify the effect of listening to the fractal tones on the underlying stress response would be beneficial.

Conclusion

The findings from this cohort study support the use of sound therapy in addition to educational counseling.

The use of fractal tones seems to provide significant tinnitus reduction, which may be due to its relaxing nature that helps to reduce tinnitus distress. Future randomized control studies are desirable to confirm the potential beneficial effects of amplification and fractal tones in tinnitus management found in this study.

Disclosure

SAC is employed at Widex.

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