

Efficacy of Tinnitus Relief System

Reg. NO.M2K02

*An Independent Project Submitted in a part fulfillment of
First Year M.Sc (Speech and Hearing),
University of Mysore, Mysore.*

**ALL INDIA INSTITUTE OF SPEECH AND HEARING
MANASAGANGOTHRI
MYSORE - 570 006.**

May-2001

DEDICATION

This project is dedicated to

my family

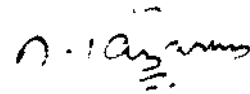
who are my world,

my everything

CERTIFICATE

This is to certify that this independent project entitled "**EFFICACY OF TINNITUS RELIEF SYSTEM**" is a bonafide work in part fulfillment for the degree of Master of Science (Speech and Hearing) of the student (Register No. M2K02).

Mysore,
May, 2001



DIRECTOR

All India Institute of
Speech and Hearing.
Mysore - 570 006.

CERTIFICATE

This is to certify that this independent project entitled "EFFICACY OF TINNITUS RELIEF SYSTEM" has been prepared under my supervision and guidance. It is also certified that this has not been submitted earlier in any other University for the award of any diploma or degree.

Guide

Dr. Rajalakshmi

Lecturer in Audiology,
Department of Audiology,

All India Institute of Speech & Hearing.

Mysore - 570 006.

Mysore,
May, 2001

DECLARATION

This Independent project entitled "**EFFICACY OF TINNITUS RELIEF SYSTEM**" is the result of my own study under the guidance of **Dr.K.Rajalakshmi**, Lecturer in Audiology, Department of Audiology, All India Institute of Speech and Hearing, Mysore and not been submitted earlier in any other University for the award of any diploma or degree.

Mysore,
May, 2001

Reg. No. M2K02

Acknowledgements

I would like to extend my heartfelt gratitude to my guide Dr.K.Rajalakshmi madam (Lecturer, Department of Audiology) for all her help and guidance.

I would like to thank Dr. Jayaram Sir (Director, All India Institute of Speech and Hearing) for allowing me to conduct this project.

My gratitude to Jobi Sir for the help without which the completion of this project would have been impossible.

I would like to thank all my friends and seniors who have helped me directly and indirectly in completing my project.

Finally I would like to thank staffs of library for all their help and guidance and *Graphics* for neat typing.

TABLE OF CONTENTS

Chapter	Page No.
I. INTRODUCTION	1-3
H. REVIEW OF LITERATURE	4-14
m. METHODOLOGY	15-17
IV. RESULTS AND DISCUSSION	18-21
V. SUMMARY AND CONCLUSIONS	22 - 23
REFERENCES	24 - 27
APPENDIX	28-31

INTRODUCTION

Mc Fadden (1982) defined tinnitus as the conscious experience of sound originating in the head.

It is often referred to as 'ringing in the ears'. It can also take the form of hissing, roaring, whistling, chirping or clicking.

The causes of tinnitus can be psychological (stress), neurological (meningitis), Vascular (anemia), metabolic (hyperthyroidism), medical (temporomandibular joint problems), or otologic (meniere's disease) - Schleuning (1998).

The tinnitus can be unilateral or bilateral, intermittent or constant, with single or multiple tones, it can be subtle or life shattering level. The severity of tinnitus depends mainly on one factor, the psychological reaction of the patient. This is why some patients are very upset by tinnitus sounds that are seldom very loud (Fowler, 1943; Fowler and Fowler, 1955).

All too often tinnitus patients have been turned away by the health care professionals with the statement, "nothing can be done for tinnitus; you will have to learn to live with it". Thus to these patients statements such as "I think we may be able to help you" are largely sought for words of encouragement. And all too often patients who are grateful for positive attention are apt to overestimate the amount of tinnitus reduction actually produced (Vernon, 1998).

Many treatment approaches have been tried to cure or reduce tinnitus. The efficiency of any treatment approach cannot be anticipated, because of the poor understanding of the physiological basis of tinnitus. Majority of the studies have been focussed on masking. The follow-up studies on masking reveal that only a small percentage of patients who have tinnitus obtain relief through the use of a masker (Roeser and Price 1980; Rose 1980; Schleuning Johnson and Vernon 1980).

Studies on combination approach (Tinnitus retraining therapy) report better benefit than masking alone (Sheldrake and Hazell, 1992; Jastreboff, Gray and Gold, 1996).

Both specific (reduction in tinnitus) as well as non specific (psychological) benefits has been reported.

The present study attempts to find out the efficacy of the audio CD manufactured by personal growth technologies. This product claims specific (reduction in tinnitus) and non-specific (psychological) benefits.

Aim of the project:

1. To find out the effect of combining masking noise with relaxation music in masking,
2. To do a follow-up study on patients provided with the recorded sample of the tinnitus relief system, ie., to check the long-term benefit from the new approach to masking and
3. To find out the factors affecting the benefit.

Need for the study:

Many studies have been conducted to find out the efficiency of tinnitus masking units, but very few on environmental masker blended with relaxation music to relieve the tinnitus and associated problems.

This project will highlight on the benefits other than passive relief from tinnitus obtained on using the combination.

REVIEW OF LITERATURE

Treatment of tinnitus:

Tinnitus is a widespread medical problem that at present is treatable in a variety ways but is not curable (Tyler and Baker, 1983).

I. PSYCHOLOGICAL APPROACH:

Most psychological treatment approaches have a common goal. This is not to cure the tinnitus but to relieve the emotional distress associated with the tinnitus.

The effectiveness of psychological counselling, relaxation therapy, biofeedback, and to some extent hypnotherapy has been assessed in careful clinical trials. It is common for patients who have undergone one or another of these psychological therapies to report improvements in the unpleasant emotions associated with their tinnitus.

(Scott, Lindberg, Lyttkens and Melin, 1985; Jakes, Hallam, Chambers and Hinchcliffe, 1985; Marks, Karle and Onisphorou, 1985; Coles, 1987).

II. FRINGE MEDICINE: Many fringe medical treatments have given reported benefit, usually only anecdotally

(i) Ginkgo biloba extract: Obtained from the leaves of the maidenhair tree, has been used for the last 2 decades for treatment of chronic cerebrovascular insufficiency and peripheral arterial disease, with some claims of success including improvements in vertigo and tinnitus. Sprenger (1986) studied its effects on hearing and tinnitus, and reported abolition of tinnitus in 36% and reduced tinnitus in 15%.

(ii) Acupuncture: In view of more somatopsychic nature of tinnitus, it might be expected that acupuncture could sometimes be beneficial. Two double blind cross-over trials have been carried out. Hansen, Hansen and Bentzen (1982) found no significant improvement with acupuncture in 17 patients. Marks, Emery and Onisiphorou (1984) found a slight temporary improvement in 5 out of 14 patients. It seems that for the general tinnitus sufferer, acupuncture does not have much to offer.

(iii) Intravenous lignocaine: Double - blind placebo-controlled cross - over trial by Martin and Colman (1980) has proved both the subjective and objective effectiveness of intravenous lignocaine.

Melding, Goodey and Thome (1978) reported that over 50% of the patients experience at least 50% reduction of their tinnitus after intravenous injection of lignocaine though, the relief is usually of too short a duration (few hours).

III PHARMACOLOGICAL TREATMENT:

(1) Aspirin: Aspirin is known to suppress spontaneous OAE (oto acoustic emissions) - McFadden and Plattsmier (1984) and can be used to treat tinnitus due to these.

(2) Quinine: Quinine is a possible alternative with fewer undesirable side effects than aspirin-Baskill and Coles (1992).

IV SUPPRESSION:

(I) Electrical suppression:

Study by Hazell, Jastreboff, Meerton and Conway (1993) has shown that a lowfrequency, sinusoidal electrical stimulation through a round-window electrode can be useful in tinnitus seperation.

Electrical stimulation of the ear as a treatment for tinnitus remains a potential avenue of further development. At the other extreme, external stimulation rarely seems to confer useful benefit (Coles, 1997).

(ii) Magnetic suppression:

Takeda (1987) reported reduction of tinnitus in 66% of ears by means of a small powerful magnet placed deep in the ear canal. However, in a subsequent study Coles, Bradley, Donaldson, and Dingle (1991) reported no significant benefit in a double - blind placebo-controlled study. It would not seem that this form of cochlear stimulation is likely to achieve worthwhile clinical results.

(iii) Electromagnetic suppression:

Double-blind Placebo-controlled study by Roland et al (1993) reported 45% Patients who underwent trial improved on the active device, but only 9% on the placebo. In the present juncture, it seems to be a harmless, sometimes helpful and inexpensive therapy for patients with tinnitus resistant to other treatment to try for themselves.

V. SURGERY:

There have been many analyses of the results of destructive operations on the internal ear, and of section of the VIIIth nerve for conditions often associated with tinnitus. In a significant proportion of cases, the tinnitus has not been alleviated by surgery or has even been made worse. It would be therefore seem that, with very few exceptions, surgery is not advisable where tinnitus is the primary indication - McFadden (1982).

VI. COMBINATION:

Tinnitus retraining therapy:

Sheldrake and Hazell (1992) reported that after 1-2 years of retraining therapy, the tinnitus was having less effect on 94% of 17 patients, and in the group of 36 patients after 2-4 years of therapy, tinnitus was worse in only 3%. The same in 22%, less in 42% and not noticed any longer in 33%.

Similar results, was reported by Jastreboff et al (1996) where 102 subjects received the full TRT (ie., tinnitus retrainers / hearing aids plus directive counselling) and 22 received only the first session of counselling without any devices. In the group which received the full treatment, 79.7% were reported to have improved, whereas in the other group, the improvement was 18.2%. The improvement was in terms of level of annoyance and awareness.

VII. PROSTHETIC:

(i) Cochlear implants:

Cochlear implant studies conducted by Ito and Sakakihara (1998) resulted in the abolishment of tinnitus in 44%, suppression in 39%, no change in 11% and aggravation in 6%.

(ii) FM Masking:

Studies conducted by Vernon and Schleuning (1978) with FM masking as a treatment to tinnitus showed 67% complete relief but resulted in disruption of speech reception.

(iii) Masking:

The modern era of therapeutic masking only began when Vernon (1978) started to fit hearing aid-like devices designed to produce a noise in the ear.

Tinnitus masking can be used in two ways viz; complete masking and partial masking.

It is a common misconception that the scope of tinnitus masking is limited to complete masking of tinnitus symptoms through the application of relatively high level sound.

Partial masking, or the process of suppressing a significant percentage of tinnitus with relatively low level sound, is commonly practiced in the field of masking.

Types of masker:

The two main kinds of wearable masker are the ear-canal and behind-the-ear instruments. There is also the combination instrument - a hearing aid with a masker built into it, for those patients who need both amplification and masking. In addition to the above wearable instruments, considerable relief can be obtained from the use of a variety of environmental noise sources. Simple advice to try using a radio, cassette player, record player or TV can be very helpful, provided the material is not too intrusive or demanding. Some useful tape recordings, like seashore noise etc., are available. At night, more meaningless and continuous noise is needed.

Residual inhibition:

Total or partial inhibition of tinnitus following acoustic simulation was originally one of the main objectives in use of tinnitus maskers. Residual inhibition is seldom achieved with the usual broad-band noise emitted by tinnitus maskers, such that when it occurs in practice it is regarded as little more than an unexpected bonus. It is also only poorly predicted by residual inhibition tests

(Hazell ,et al.,) Researchers have looked for the optimal noise spectrum and temporal characteristics for achieving residual inhibition but their findings have been more confusing than helpful. Terry, Jones, Davis and Slater. (1983) found that the frequency producing maximal residual inhibition is usually lower than the tinnitus frequency by as much as an octave, or two in some cases.

Efficiency of masking: A review

In spite of the greater effectiveness and acceptability of retraining therapy, there is still some place for the use of masking, where in many clinics it is used as the principal means of helping many tinnitus patients. It is used during retraining therapy as a temporary palliative in periods when the tinnitus is particularly troublesome. There are other patients whose tinnitus is only intermittently present or troublesome and who are sufficiently helped at these times by masking.

Shailer, Tyler and Coles (1981) conducted a study where they measured the level of noise required to mask tinnitus in subjects with sensorineural tinnitus. The noise was centered on the estimated pitch of tinnitus and the level required to just mask the tinnitus was measured for different masker bandwidths. The result showed that 33.33% of the tinnitus subjects showed masking functions that were similar to those observed in normal hearing subjects with "simulated" tinnitus. The other 66.67% however required masking levels that were either independent of masker bandwidth or showed an optimum band width which required less masker level than any other masker band width. Results suggested that the noise characteristics for tinnitus masker may be beneficially tailored for some individuals with tinnitus.

Penner (1987) conducted two experiments to check the effect of masker frequency on masking. In the first experiment, for subject with sensorineural

tinnitus, the masking of tinnitus was primarily dependent on the masker intensity and nearly independent of masking frequency.

In the second experiment, for subjects with normal hearing the central masking of continuous tone was primarily dependent on the intensity of the contralateral masker, and nearly independent on masker frequency.

The results of the experiment reported some implications for the clinical procedure involved in fitting tinnitus masker for some subjects. Since a tone of nearly any frequency can make the tinnitus inaudible, identifying the pitch of the tinnitus and shaping the tinnitus masker around this frequency is not always essential. It might be possible to choose masker that are well outside the region of speech frequencies.

Kemp and George (1992) conducted two experiments in which eight listeners used external sound to mask the tinnitus induced by a 95 dB SPL tone presented for one minute. Results indicated that wider bandwidth noises were more effective masker than noises of critical bandwidth, which in turn, were more effective than tonal masker. Contralateral masker were often effective, but less so than ipsilateral masker.

Erlandson, Ringdahl, Hutchins and Carlsson (1987) conducted a study where 80% (ie 17 out of 21) of patients with severe tinnitus were asked to rate their tinnitus intensity during a baseline period, during treatment with portable masker, and during a period with a comparable placebo apparatus. Group analysis showed no significant difference between any of the three periods. Seven patients showed significantly reduced tinnitus intensity rating during the masker period, five of them also did so during the placebo treatment; After each

of the treatment periods, the 21 patients answered a questionnaire about the specific and general beneficial effects experienced during the treatment. Results showed that specific effects were more pronounced during masker and non-specific effect during placebo treatment.

Smith, Lutman and Coles (1991) conducted a study where ten experienced tinnitus masker users having stable tinnitus overtime compared four widely different noise bands as potential masker in a laboratory environment. No reliable individual preferences could be found, and most of the noises were acceptable to most of the subjects. A wide-band noise was marginally most frequently preferred. According to the study, there was no indication that individual tailoring of the frequency spectra of tinnitus masker is required to achieve acceptable masking. Most of the subjects chose noise levels, for therapeutic masking that only partially masked their tinnitus. This suggests that trial of tinnitus masker should be given even for patients who have high minimal masking levels.

The study conducted by Penner (1988) explored the relation between changes reported in the perception of the loudness of tinnitus after noise exposure and changes measured in matches to the loudness of tinnitus after noise exposure. Pre exposure assessment of the loudness of tinnitus was followed by monaural exposures to wide band Gaussian noise, after which a pulsed 200 ms tone was presented either ipsilateral or contralateral to the exposed ear. A measure of the post exposure tinnitus magnitude was computed by combining data across noise exposures. For 50% of the subjects the pre and post exposure magnitude did not differ significantly, even though the judgements indicated that the pre and post exposures loudness of the tinnitus had changed. This study raised the possibility that some loudness judgements reflect variability in the tinnitus and not the effect of the noise on tinnitus.

The study conducted by Terry and Jones (1981) used the method of the magnitude estimation to compare the annoyance ratings of 36 different masking sounds obtained from a group suffering from tinnitus with ratings from normal hearing group in an attempt to assess the acceptability of potential tinnitus masker. The key findings were as follows:

- a. Bandpass noise rated less annoying than tones.
- b. The annoyance of bandpass masker increased with bandwidth.
- c. Interrupted masker were rated more annoying.
- d. Control over the centre frequency and the bandwidth of a noise masker was important in optimizing the acceptability of the tinnitus masker.
- e. When complete masking of the tinnitus is difficult a reduction in annoyance may be possible by partial masking.

Dineen, and Doyle (1997) conducted a study to examine the interaction between the characteristics of individual tinnitus sufferers and the effectiveness of the methods used to assist them. Four differing tinnitus management programs were tried and the related changes in the tinnitus. Perception was reported three months after the management. According to the results subjects receiving low level white noise stimulation reported greater improvement in the tinnitus coping ability than subjects who received information and relaxation training. There was no associated improvement in tinnitus awareness as reported.

Tyler, Conrad-Armes and Smith (1984) conducted a study giving preliminary results of attempts to measure the perception of tinnitus after the termination of the masker. A minimum level to mask tinnitus was determined for a 1 second masker in 10 subjects with sensorineural tinnitus. A continuous masker was then presented to the ear ipsilateral to the tinnitus. At the termination of the masker, subjects were required to press a button to indicate

when their tinnitus first returned and a second when it returned to normal loudness. Results showed that at low level and short duration masker, the tinnitus typically was heard immediately after the masker termination. At higher levels and longer durations different responses were observed, however masker frequency had little effect.

Letowski and Thompson (1985) conducted a study where they compared annoyance by masking tinnitus using continuous and interrupted white noise and found the following two factors:

- I. Interrupted noises were more annoying than the continuous noise.
- II. Perception of annoyance in both groups was very similar at the highest level.

The results suggest that despite the advantages of interrupted noise, it is not suitable as a tinnitus masker since it is more annoying than continuous noise.

Wedel, Wedel and Walger (1998) conducted a study reporting on the acoustical therapy with tinnitus maskers and with hearing aids for patients with severe disabling chronic tinnitus. To compare the benefits of hearing aids or tinnitus maskers over a period of at least one year, the patients were examined for the features of tinnitus, masking effects during use, residual inhibition effects after use, and subjective scaling of the therapeutic efficiency. In 62.7% of the patients a partial masking via environmental noises could be produced by hearing aids and 18.5% by tinnitus masker. Complete masking was reported by 17.3% of the patients using a hearing aid and 76.9% using tinnitus masker. About 94.7% of the hearing aid users and 71.3% of patients with tinnitus maskers reported a partial or complete residual inhibition lasting less than 30 seconds and 0.3% of the hearing

aid users and 15.7% of patients with tinnitus maskers reported residual inhibition lasting about 60 seconds. 13% of patients using tinnitus maskers reported residual inhibition effects lasting up to 2 to 3 hours.

Roeser and Price, (1980) conducted a study to assess the efficiency of the tinnitus masking units as a means of providing active and passive relief for patients with problematic tinnitus. A questionnaire was used for this purpose. Results reported that 26% of the patients who were felt to be candidates for masking units reported some form of relief from their tinnitus.

Rose (1980) in a follow up study reported that out of 31 individuals who rented tinnitus masker after otologic and audiologic examination and consultation, 10 of 31 purchased instruments after a 30 days rented period. 8 of 10 who purchased were contacted either by letter or by phone. 2 of 8 were using their instruments on a regular basis. One was using his masker sporadically and was not positive about the help received.

These followup findings revealed that only a small percentage of patients who have tinnitus obtain relief through the use of a masker.

Schleuning, Johnson and Vernon (1980) conducted a follow up study of two groups of tinnitus patients in an attempt to evaluate the tinnitus masking program. The first group encompassed 493 patients who were seen in the first three years of the program, and the second group comprised 105 patients seen during the first part of 1979. According to results larger number of patients were recommended to be fit with tinnitus masker. In the first group 75% of the patients purchased them or experimented with them for a period of time. Only 30% of the patients were receiving some relief from their tinnitus. The success rate with tinnitus maskers was 47% in the second group.

METHODOLOGY

Subjects:

Out of the number of subjects who reported to All India Institute of Speech and Hearing with a complaint of severe tinnitus, 10 subjects were selected for the study with the following criteria.

1. Patients from either sex in the age range of 20-75 years.
2. Persons with hearing sensitivity preferably within near normal limits.
(Within 30 dB)
3. Persons with persistent history of tinnitus.
4. Persons reporting tinnitus as distressing.
5. Persons who were positive about the result.

Instrumentation:

1. OB 822 audiometer
2. Computerized CD player
3. Audio TRS CD sample - manufactured by Personal Growth Technologies.

Test environment:

The assessment were carried out in a partially sound treated room

History taking:

The following details were collected:

1. The time/severity course of the tinnitus, together with a note of any apparent or suspected triggering factors.
2. The localization and the effects of the tinnitus.
3. The time of day or night when the tinnitus is most troublesome.
4. Whether there is effect of environmental sound in masking or reducing the loudness of the tinnitus.

ASSESSMENT OF TINNITUS:

1. Pitch match
2. Loudness match
3. Assessment of duration of residual inhibition.

1. Pitch Match:

The appropriate pitch of the tinnitus for each subject was determined by a matching procedure. The reference signal (puretone, narrow band noise, wideband noise) was presented to the ear and opposite to the side where the tinnitus was being perceived.

The subject was instructed to indicate the sound that closely resembled their measured tinnitus.

2. Loudness match:

To measure loudness, a balance technique was used with the indicated sound presented to the opposite ear, where the tinnitus was being measured. The sound was increased in the opposite ear until the subject first heard the sound and this is threshold for noise band. Then the sound was increased until the subject indicated that it was equally "loud" to their tinnitus. The difference between the threshold and when the external sound was equally loud to the tinnitus is the loudness of the subject's tinnitus.

The pitch and loudness matching was not carried out in subjects with bilateral tinnitus due to inaccuracy of the measurement.

3. Duration of residual inhibition:

Depending upon the subjects comfortable level, the noise was presented either at the level that completely masked the tinnitus or at the level that partially masked the tinnitus. This was presented for two minutes and at the termination of the noise the subject was asked to report the loudness perception of the tinnitus. They were given options to answer from:

1. Increase in the loudness
2. No change in the loudness
3. Reduction in the loudness
4. Complete disappearance of tinnitus.

In the latter two instances, the duration of inhibition was noted.

Residual inhibition was not the criteria for selecting patients for trial therapy. Subject selections was largely based on the willingness of the subject. Based on the pitch match, the tracks were selected and recorded on audio cassette which was given to the subject to be used at home. A minimum of 30 minutes per day listening was advised. Follow up was done after 15 days or > 1 month with a questionnaire.

RESULTS AND DISCUSSION

The following factors were compared across subjects to assess the overall benefit.

- | | |
|------------------------------------|---|
| 1. Loudness | Soft, Loud, Very loud. |
| 2. Effort to ignore | Easily, With effort, Not able to ignore |
| 3. Interference with concentration | Yes, No |
| 4. Increase in tension | Yes, No |
| 5. Interference with sleep | Yes, No |
| 6. Depression | Yes, No |
| 7 Use of cassette | < 30min, >30 min |
| 8. Reduction in tinnitus | Yes, No |
| 9. Other benefit | Yes, No |
| 10. Usage at present | Yes, No . |

Table showing the results:

Subjects /Factors	1	2	3	4	5	6	7	8	9	10
1	L	WE	N	Y	Y	Y	30m/d	C	R+IS	Y
2	S	E	N	N	Y	N	<30m/d	P	X	N
3	VL	WE	N	Y	Y	N	>30m/d	P	X	N
4	L	E	N	Y	N	N	NT	P	R	N
5	VL	WE	Y	Y	Y	N	30m/d	P	R + IS	Y
6	S	E	Y	Y	Y	Y	30m/d	P	R + IS	Y
7	S	E	N	Y	Y	N	>30m/d	P	R + IS	Y
8	S	E	N	N	Y	N	<30m/d	C	X	N
9	S	E	N	N	Y	N	<30m/d	C	R	Y

Key to the table:

- 1 VL = Very Loud, L = Loud, S = Soft
- 2 E = Easily, W.E = With Effort
- 3, 4, 5, 6 and 10 Y = Yes, N = No.
- 7 m/d = Minutes per day.
- 8 P = Partial, C = Complete
- 9 R = Relaxation, IS = Induces Sleep, X = No benefit.
- N.T No trial / Immediate benefit was assessed.

ANALYSIS:

- > Five out of nine reported their loudness as soft and two out of nine reported it as loud and very loud.
- > Six out of nine reported that they could ignore their tinnitus easily and three reported that they could ignore with effort.
- > Seven out of nine reported no interference with concentration and two out of nine reported some interference
- > Three out of nine reported negatively for increase in tension and six reported associated increase in tension
- > Only one of the subjects reported no interference in sleep whereas eight reported interference with sleep.
- > Seven out of nine did not report any depression whereas two reported associated depression
- > Two reported that they listened to the cassette for > 30min/day, three reported that they listened to approximately 30 min/day (only before sleeping) and three reported that they listened to the cassette for less than 30min/day. One of the subjects did not collect the cassette.

- > Three out of nine subjects reported reduction in tinnitus during use and six used it at partial masking level.
- > Four subjects reported their benefit as relaxing and sleep inducing and two reported the benefit as relaxing. Three subjects reported that they did not get any benefit.
- > Five out of nine subjects are using the audio cassette at present whereas four are not using it at present.
- > All the six subjects who benefited and are using the cassette at present were found to have realistic expectations.

DISCUSSION:

The results obtained supports the studies conducted, mainly with the combination of different approaches.

The results shows that the benefit obtained from tinnitus relief system is definitely better than that obtained from conventional masking.

(Roeser and Price, 1980; Rose, 1980; Schleuning Johnson and Vernon, 1980)

Vernon and Schleuning (1978) reported that 67% of the subjects obtaining complete relief through the use of F.M. masking.

In the present study 6 of 9 i.e 67% reported partial relief and 3 of 9 i.e 35% reported complete relief.

Jastreboff (1996) reported 79.7% of the subjects reported improvement through the combination of tinnitus retrainers plus directive counselling. In the present study 6 of 9 i.e., 67% reported benefit in terms of relaxation and sleep.

Dineen et al. (1997) reported that in 63% of the subjects who received information plus white noise, the coping ability increased. In the present study 6 of 9 i.e 67% reported reduction in tension.

Finally the present study supports the double-blind clinical study conducted by the inventors to test the effectiveness of the tinnitus relief system. The results showed that 70% of the subjects noted a reduction in their tinnitus during use and also reported that the program helped them relax and get a better nights sleep. In the present study all the subjects experienced partial / complete relief during use, whereas 6 of 9 i.e. 67% reported that they got relaxation plus a better nights sleep.

It was found that expectation of the subject played a major role in determining the efficacy of the treatment.

SUMMARY AND CONCLUSION

- As frustrating as it is, there's no cure for tinnitus. The best one can hope for a temporary relief from the tinnitus. Many treatment approaches have been tried in attempts to cure or reduce tinnitus, ranging from medical to psychological. The efficacy of these treatment techniques vary across subjects. Different studies show contradicting results regarding the benefit of each approach.
- Tinnitus masking pioneered by Dr. Jack vernon is essentially the process of sonically "covering over", and thereby reducing the perceived intensity of the tinnitus sound. Many studies have been conducted to highlight on the factors affecting the efficacy of masking.

Studies have shown better results with combination of techniques like tinnitus retraining therapy and masking plus psychological approach. The benefits include specific as well as non-specific relief.

- " Tinnitus relief system manufactured by personal growth technologies provides relief through a unique combination of masking, distraction, and stress reduction.
- The aim of the present study was to evaluate the efficacy of this product as well as to find out the factors affecting the efficacy subjects in the age range of 20-75 years with distressing tinnitus participated in this study. The appropriate tracks were selected by pitch matching method. The subjects were counselled regarding the use of the recorded case etc. followup was done with a questionnaire after the trial period of 1-2 months.

- Results supported the studies on combination approach i.e., tinnitus masking and psychological approach.
- Results of the present study also suggested that subjects with realistic expectations benefited more.

Conclusions:

In the present study 67% of subjects experienced relief through the tinnitus relief system from the following associated problems:

1. Stress
2. Sleep disturbance
3. Reduced concentration

The present study also found that the attitude of the subject plays an important role in determining the efficacy of the treatment. The results cannot be generalized for a large population as only 9 subjects were included for the study.

It is probably true that in a random sample of patients with tinnitus only a few patients can be completely cured.

However, patients with tinnitus can definitely be improved by different measures even if they are not completely cured.

The selection of the appropriate measure is upto the audiologist.

REFERENCES

- Baskill, J.L. and Coles, R.R.A. (1992). Current studies on spontaneous emissions and tinnitus. In: Tinnitus 91: proceedings of the Fourth International tinnitus Seminar, Bordeaux, 1991, J-M. Aran and R. Dauman, Amsterdam: Kugler, 79-83.
- Coles, R., Bradley, P., Donaldson, I. and Dingle, A. (1991). A trial of tinnitus therapy with ear-canal magnets. *Clinical otolaryngology*, 16, 371-372.
- Coles, R.R.A. (1987). Tinnitus and its management. In A.G. Kerr., J. Groves and D. Stephens Scott-Brown's otolaryngology: Adult Audiology (Edn. 5), 368-414. Jordan Hill Butterworth and Co. (Publishers) Ltd.
- Coles. R.R.A. (1997). "Tinnitus". In A.G. Kerr and D. Stephens. Scott Brown's otolaryngology: Adult Audiology (Edn:6). 2/18/1-2/18/34. Jordan Hill: Reed Educational and Professional Publishing Ltd.
- Dineen, R. and Doyle, J. (1997). Managing tinnitus: A comparison of different approaches to tinnitus management training. *British Journal of Audiology*, 31,331-344.
- Erlandsson, S., Ringdahl, A., Hutchins, T., and Carlsson, S.G. (1987). Treatment of tinnitus: a controlled comparison of masking and placebo. *British Journal of Audiology*, 21, 37-44.
- Fowler, E.P. (1943). Control of head noises: their illusions of loudness and of timbre. *Archives of otolaryngology*, 39, 498-503.
- Fowler, E.P. and Fowler, E.P. (1955). Somatopsychic and psychosomatic factors in tinnitus, deafness and vertigo. *Annals of Otology, Rhinology and Laryngology*, 64, 29-37.
- Hansen, P.E., Hansen, J.H. and Bentzen, O. (1982). Acupuncture treatment of chronic unilateral tinnitus - a double blind cross-over trial. *Clinical Otolaryngology*, 7, 325-329.
- Hazell, J.W.P., Jastreboff, P.J., Meerton, L.E. and Conway, M.J. (1993). Electrical tinnitus suppression: Frequency Dependence of Effects. *Audiology*, 32, 68-77.

- Ito, J., and Sakakihara, J. (1998) "Suppression of tinnitus by cochlear Implant" In J.A. Vernon. Tinnitus: Treatment and Relief. 91-98. Needham Heights: Allyn and Bacon.
- Jakes, S.C., Itallam, R.S., Chambers, C.C. and Hinchcliffe, R. (1985) A factor analytical study of tinnitus complaint behaviour. *Audiology*, 24, 195-206.
- Jastreboff, P.J., Gray, W.C. and Gold, S.L. (1996). Neurophysiological Approachs to Tinnitus Patients. *American Journal of Otology*, 17, 236-40.
- Kemp, S. and George, R.N. (1992). Masking of tinnitus induced by sound. *Journal of speech and hearing research*, 35, 1169-1179.
- Letowski, T.R. and Thompson, M.V. (1985). Interrupted noise as a tinnitus masker: An annoyance study. *Ear and Hearing* 6(2), 65-75.
- Marks, N.J., Emery, P. and Onisiphorou, C. (1984). A controlled trial of acupuncture in tinnitus. *Journal of Laryngology and Otology*, 98, 1103-1109.
- Marks, N.J., Karle, H. and Onisiphorou, C. (1985). A controlled trial of hypotherapy in tinnitus. *Clinical otolaryngology*, 10, 43-46.
- Martin, F.W. and Colman, B.H. (1980). Tinnitus: a trouble-blind crossover controlled trial to evaluate the use of lignocaine. *Clinical Otolaryngology*, 5,3-11.
- McFadden, D. (1982) tinnitus: Facts, theories and treatments. Washington, DC: National Academic Press.
- McFadden, D. and Plattsmier, H.S. (1984). Aspirin abolishes spontaneous otoacoustic emissions. *Journal of the Acoustical Society of America*, 76, 443.447.
- Melding, P.S., Goodey, R.J. and Thome, P.R. (1978). The use of intravenous lignocaine in the diagnosis and treatment of tinnitus. *Journal of Laryngology and otology*, 92, 115-121.
- Penner, M.J. (1987). Masking of tinnitus and central masking. *Journal of Speech and Hearing Research*, 30, 147-152.

- Penner, M.J. (1988). Judgements and measurements of the loudness of tinnitus before and after masking. *Journal of Speech and Hearing Research*, 31, 582-587.
- Roeser, R.J. and Price, D.R. (1980). Clinical experience with tinnitus maskers. *Ear and Hearing*, 1 (2), 63-68.
- Roland, N.J., Hughes, J.B., Daley, M.B., Cook, J.A., Jones, A.S. and McCormick, M.S. (1993). Electromagnetic stimulation as a treatment of tinnitus: a pilot study. *Clinical Otolaryngology*, 18, 278-281.
- Rose, D.E. (1980). Tinnitus maskers: a follow-up. *Ear and Hearing*, 1(2), 69-70.
- Schlenning, A. (1998). "Medical aspects of tinnitus" In J.A. Vernon. *Tinnitus: Treatment and Relief*. 20-27. Needham Heights: Allyn and Bacon.
- Schleuning, A.J., Johnson, R.M. and Vernon, J.A. (1980). Evaluation of a tinnitus masking programme; a follow-up study of 598 patients. *Ear and Hearing*, 1 (2), 71-74.
- Scott, B., Lindberg, P., Lyttkens, L. and Melin, L. (1985) psychological treatment of tinnitus: an experimental group study. *Scandinavian Audiology*, 14, 223-230.
- Shailer, M.J., Tyler, R.S. and Coles, R.R.A. (1981). Critical masking bands for sensorineural tinnitus. *Scandinavian Audiology*, 10, 157-162.
- Sheldrake, J.B. and Hazell, J.W.P. (1992). Maskers versus hearing aids in the prosthetic management of tinnitus. In: *Tinnitus 91: Proceedings of the Fourth international Tinnitus Seminar, Bordeaux, 1991*, Edited by J-M. Aran and R. Dauman. Amsterdam: Kngler, pp.395-399.
- Smith, P.A., Parr, V.M., Lutman, M.E. and Coles, R.R.A. (1991). Comparative study of four noise spectra as potential tinnitus maskers. *British Journal of Audiology*, 25, 25-34.
- Sprenger, F.H. (1986). Innenohrschwerhörigkeit. gute therapieergebnisse mit ginkgo biloba. *Arztliche Praxis*, 12, 938-940.
- Takeda, H. (1987). Magnetic therapy for tinnitus. *Otologiafukuoka*, 33, 700-706.

- Terry, A.M.P. and Jones, D.M. (1986). Preference for potential tinnitus maskers: results from annoyance ratings. *British Journal of Audiology*, 20, 277-297.
- Terry, A.M.P. and Jones, D.M., Davis, R. and Slater, R. (1983). Parametric studies of tinnitus masking and residual inhibition. *British Journal of Audiology*, 17, 245-253.
- Tyler, R.S. and Baker, L.J. (1983). Difficulties experienced by tinnitus sufferers. *Journal of Speech and Hearing Disorders*, 48, 150-154.
- Tyler, R.S., Conrad-Armes, D. and Smith, P.A. (1984). Postmasking effects of sensorineural tinnitus: a preliminary investigation. *Journal of Speech and Hearing Research*, 27, 466-474.
- Vernon, J. and Schleuning, A. (1978). Tinnitus: A new management. *The laryngoscope*, 88, 413-419.
- Vernon, J.A. (1998). In J.A. Vernon tinnitus: Treatment and Relief. Needham Heights: Allyn and Bacon.
- Wedel, H.V., Wedel, V.C.V and Walger .M. (1998). "Tinnitus masking with tinnitus maskers and hearing aids: A longitudinal study of efficacy from 1987 to 1993." In J.A. Vernon. Tinnitus: Treatment and Relief. 187-192. Needham Heights: Allyn and Bacon.

APPENDIX

ABOUT THE PRODUCT

TINNITUS RELIEF SYSTEM (Manufactured by Personal Growth Technologies):

Utilizing a patented recording technology called 3-D virtual sound they have created the tinnitus relief system. It is comprised of a wide array of enjoyable recordings that have been proven effective for relieving tinnitus and the stress often associated with it.

What is 3-D Virtual Reality Sound by High Definition Audio (HDA)?

Over dozen years in development, High Definition Audio's sound capturing technology blends the geometry of the human torso with the characteristics of the human ears to capture and process sound the same way the human body does. Based on the human sound processing principles of not only using the structural mechanisms in the ear, but also integrating human body reception that mix a variety of tones and frequencies, High Definition Audio's patented technology produces extremely accurate, rich and vivid three-dimension sound.

Due to the Ultra-realistic quality of sounds capturing by the technology, listeners perceive the recording to be "real". HDA's patented technology is not an artificial created audio effect. It "Captures" the sound in its natural state and delivers it with no loss of dimension or detail.

High Definition Audio technology uses a single ended encoding process and its compatible with all playback equipment.

How it works?

The Tinnitus Relief System (TRS) is comprised of entertaining soothing, natural recordings that are digitally mixed with very sophisticated wave composites (not static with noise) that often provide relief through a unique combination of masking distraction, and stress reduction.

The Tinnitus Relief System (TRS) consists of 5 different frequency-low, mid to low, mid to high, high and broad range. Within each different frequency there are three section-nature sound, nature sounds blended with soft classical music, or nature sound blended with contemporary easy-listening music. This provides you with 15 different choices that are available in the cassette tape or CD format.

About:

The inventors had been at work perfecting a revolution audio technology that captured high dimensional and accurate sound with an uncanny presence. During the course of the technology development, a variety of beta-tests were performed, capturing a wide range of sounds and events that were presented together in compact CD.

Listeners of the sound compilation CD marveled at the vivid, life-like quality of the recordings. The reaction to the sounds the technology captured was phenomenal. Listeners reported feeling that they were in the middle of the event they were listening to on playback. One listener reported that he had finally found the one thing that seemed to relieve his severe tinnitus.

At the time, Doug Magyari, the primary inventor of the audio technology, had never heard of tinnitus. Upon learning about tinnitus and the incapacitating impact it has on many people's lives, Magyari was intrigued and wanted to explore the possibility of this new technology providing relief to those with tinnitus. During this time, Magyari learned that his father, too had tinnitus. Thus, Magyari became even more determined to attempt to explore his new technology providing a relief for those with tinnitus. Applying the same attention to detail and problem solving techniques he had devoted to the development of the audio technology and his inventions, Magyari immersed himself researching tinnitus.

With the assistance of Dr. Michael LaRouere of the Michigan Ear Institute, an initial focus group of people with tinnitus was conducted. Magyari spent months assessing the common factors of the relief and built his test program. A study was conducted with a focus group of people with tinnitus given the programs to determine their initial effectiveness. Over 70% reported finding an effective program within the group of 5 programs.

In 1994, the U.S. Food and Drug Administration granted the program clearance to make a medicine claim. The process of obtaining FDA clearance took two years and a double blind clinical study to test the effectiveness of the products.

The tinnitus Relief System was developed for close to 16 years. The 15 program titles in five frequency ranges integrate distraction techniques with layered complex nature and music waveforms. The Tinnitus Relief System utilizes 3-D virtual reality Sound by High Definition Audio; the audio technology which Magyari invented.

Magyari was meticulous in recording the nature sound used in the programs. Over 100 ocean recordings were made, with Magyari traversing the Eastern Coast of U.S.A. until he captured what he likes to term the calm after the storm", Ocean recording in Florida following a heavy storm. After recording hundreds of waterfalls and brooks, Magyari found the perfect sound in isolated parts of Northern Michigan. In his detail discussion with the people with tinnitus, Magyari found many-claimed relief while in the shower or while sitting at the bow of a boat.