AN EVALUATION OF TINNITUS MASKER EFFECTIVENESS

by

Lori J. Leibold

Department of Communicative Disorders

Submitted in partial fulfilment
of the requirements for the degree of
Master of Science

Faculty of Graduate Studies
The University of Western Ontario
London, ON
May, 1997

ABSTRACT

The effectiveness of tinnitus maskers were investigated. Previous studies have suggested that tinnitus maskers may provide tinnitus relief, but the number of patients who benefit from tinnitus maskers is unclear. Eighteen subjects, 44 to 68 years of age, were selected to participate in the study. Subjects were randomly assigned to receive either a tinnitus masker or a placebo device. After six weeks, subjects were fitted with the alternative devices. Success was determined primarily by comparing ratings of the Iowa Tinnitus Questionnaire. Results indicated no significant differences between the tinnitus masker and placebo devices. These results suggest that tinnitus maskers are not successful in the treatment of tinnitus and efforts should be made to investigate other forms of tinnitus treatment.

ACKNOWLEDGEMENTS

I would like to thank my fiancé Raj Persaud for his support over the last three years.

Thanks to Brenda Tullio for her participation in this study and patience.

Thank you to Dr. Linda Miller, Dr. Margaret Cheesman and Brenda Buckrell for their suggestions and assistance.

Special thanks to Dr. James Stouffer for his support, encouragement and time during this project.

This research was supported through funding provided by Unitron Industries Ltd. Equipment was provided by Starkey Canada.

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INTRODUCTION

The perception of an auditory stimulus in the absence of auditory stimulation is defined as tinnitus. Tinnitus patients most frequently describe tinnitus as a ringing or buzzing sound. Mild transient tinnitus is experienced by most people at one time or another and is generally not regarded as a problem. In contrast, some individuals with chronic tinnitus report that their tinnitus is a life altering condition.

There are two categories of tinnitus, objective and subjective. Objective tinnitus, a fairly rare condition, does not fit the traditional definition of tinnitus as an auditory stimulus is present and it can be heard by others. Generally, objective tinnitus results from internal blood flow. Subjective tinnitus is the more common form of tinnitus. Subjective tinnitus can be heard only by the patient.

Tinnitus is a common and often debilitating condition (American Tinnitus Association, 1986; Coles, 1984a, 1984b; National Centre for Health Statistics, 1967, 1980; Stouffer & Tyler, 1990). In the United States, a general population study indicated that 32% of the population suffered from tinnitus (National Centre for Health Statistics, 1967, 1980). In the United Kingdom, a similar study reported tinnitus prevalence to be approximately 35% (Coles, 1984b). The results of both the U.S. and U.K. data indicated that about 2% of the tinnitus sufferers report that their tinnitus is severe (Coles, 1984a, 1984b; National Centre for Health Statistics, 1967, 1980) and in the British study roughly 0.5% of the individuals suffering from tinnitus felt that the ability to lead a normal life was affected (Coles, 1984a, 1984b). The prevalence of tinnitus is even higher in the

hearing impaired, where 70-85% of individuals with some form of ear dysfunction experienced tinnitus (House & Brackmann, 1981).

Tyler and Baker (1983) administered an open-ended questionnaire to 72 members of a Nottingham self-help group. The investigators asked participants to list difficulties they attributed to their tinnitus. Problems listed by 15% or more of the participants were (a) getting to sleep, (b) persistence of tinnitus, (c) understanding speech, (d) depression, (e) annoyance, (f) confusion, and (g) dependence on drugs.

Analysis of 19,000 questionnaires mailed to a random sample of the British population indicated that tinnitus patients are affected by sleep disturbances and report a severe effect on their ability to lead a normal life (Coles, 1984a, 1984b). Coles (1984b) concluded that the prevalence of tinnitus increases with age and noise exposure.

Lindberg, Lyttens, Melin and Scott (1984) studied 1,901 patients from the departments of audiology and otolaryngology at a Swedish hospital hearing centre. Fifty-nine percent of the patients claimed that they were troubled by tinnitus. Among those patients with both a hearing loss and subjective tinnitus, 23% reported that the tinnitus was the greater problem. Thirty-eight percent of the respondents stated that the tinnitus and hearing loss were equally troublesome. The authors suggested that the extent of the problems endured by the tinnitus sufferer is obscured because tinnitus patients are often informed that no available treatment exists.

A study conducted by the American Tinnitus Association (1986) analysed 2,550 questionnaires. Thirty-eight percent characterized their tinnitus as ringing and 77% indicated that it was always present. Furthermore, 24% reported a moderate amount of

interference with their general enjoyment of life and 6% had permanently or temporarily quit work because of tinnitus.

There have been many models proposed to explain the mechanisms of tinnitus (Eggermont, 1990; Hazell, 1995; Jastreboff, 1990; Kitahara, Kitano, Suzuki & Kitajimak, 1995; Tonndorf, 1987; Zenner & Ernst, 1995). None of these models adequately account for all of the possible causes of tinnitus. It is known that tinnitus is linked with many different auditory disorders (Fowler, 1944). Therefore, it is probable that more than one model of tinnitus is necessary to explain tinnitus arising from different locations within the auditory pathways.

Clinical observations suggest that the generator responsible for tinnitus is likely a weak signal generated by a relatively small disturbance in the auditory system. Auditory Brainstem Response (ABR) data show no significant differences between tinnitus subjects and non-tinnitus sufferers. No differences have been found in resting thresholds. (Jastreboff, Ikner & Hassen, 1991). Additionally, tinnitus is not detectable in the random activity of the auditory nerve (Sininger, Eggermont & King, 1992), and except in rare cases, tinnitus is not related to spontaneous otoacoustic emissions (SOAE's) (Penner & Burns, 1987).

Peripheral mechanisms have been suggested to account for tinnitus (Kemp, 1981; LePage, 1991; Meikle, 1995). Most of the common etiologies of sensorineural hearing loss (eg. noise-induced hearing loss, Meniere's disease, ototoxic drugs, presbycusis) are associated with tinnitus. This implicates the cochlear mechanism as a possible key generator site for tinnitus, at least in those individuals whose hearing loss has a cochlear

origin (Lenarz, 1992). Also, peripheral hearing loss tends to exert a strong effect on the perceived pitch of the tinnitus (Meikle, 1995). However, malfunction at the level of the peripheral auditory mechanism can not account for all cases of tinnitus. For example, tinnitus is sometimes present in individuals with normal hearing.

In addition, several observations related to psychophysics support a central origin and/or a central representation of tinnitus. Masking studies show that tinnitus does not behave consistent with auditory sensations elicited by external stimuli (Feldmann, 1987; Hazell & Wood, 1981). For example, masking tinnitus depends only slightly on the frequency of the masker, contralateral masking is usually as effective as ipsilateral masking, habituation does not occur with tinnitus and residual inhibition is observed in some individuals. Also supporting a central origin for tinnitus is the observation that of acoustic neuroma patients, of whom nearly all report tinnitus, less than half show improvement in their tinnitus following surgery, even if the eighth nerve has been sectioned (House & Brackmann, 1981).

Similarities between tinnitus and pain have been explored (Tonndorf, 1995). Both are subjective and both may vary in quantity or character over time. Both may be masked by suitable inputs, but not in all cases. Both can be alleviated using electrical stimulation. Further, tinnitus shares many characteristics with phantom limb phenomena. For example they both mimic external stimuli, refer to specific anatomical locations, and persist in the face of deafferentiation (Melzack, 1992).

If all tinnitus was produced by an identical mechanism, one would expect a universal treatment to be effective for all tinnitus sufferers. This has not been

demonstrated. Research as well as clinical observations indicate that it is probable that more than one basic tinnitus mechanism exists.

Psychophysical measurements of tinnitus have described tinnitus loudness, pitch and other factors. A psychophysical evaluation involves measuring a particular component of tinnitus, such as loudness or masking tinnitus (Kuk, Tyler, Russell & Jordan, 1990; Penner, 1984, 1986, 1988; Penner, Brauth & Hood, 1981; Tyler & Conrad-Armes, 1983, 1984;). The magnitude of the tinnitus is generally specified in terms of the sensation level of a pure tone said to be as loud as the tinnitus (Vernon, 1976). Often the pure tone used is low frequency to ensure it is not confused with the tinnitus. Vernon (1976) reported that 69% of the patients match their tinnitus sensation level to an external tone of 10 dB SL or less. This seems surprising that tinnitus should be so annoying if its measured SL is so low. However, tinnitus clearly does not behave as an external tone of 10 dB SL. For example, it usually cannot be masked for 30 minutes by a noise loud enough to mask an external tone at 10 dB SL.

The use of either ipsilateral or contralateral masking can identify tinnitus sufferers who are good candidates for tinnitus maskers. It is difficult to determine which of ipsilateral and contralateral masking is most effective until actual clinical trials are performed. Clinically, this is achieved by having the patient indicate when an external masking noise is raised to a sufficient level to obscure the patient's tinnitus. A low or moderate level of masking is required to mask the tinnitus of patients who are good candidates to use a tinnitus masker. Patients who are not good candidates to use a masker

either require high levels of masking noise to mask their tinnitus or their tinnitus cannot be masked, regardless of masker level.

Residual inhibition occurs when the tinnitus is reduced or eliminated following the termination of a masker (Feldmann, 1971). This can also be evaluated clinically. The client is presented with an external noise stimulus that is known to mask their tinnitus. Following presentation of the noise, the client is asked to respond when their tinnitus returns and report whether it returned at the same loudness, less loudly or more loudly.

Many studies have measured tinnitus parameters by self-rating scales and psychophysical procedures. Self-rating scales have been used to measure annoyance, loudness, pitch, severity, and other factors associated with tinnitus (Axelsson & Ringdahl, 1989; Coles, 1984b, 1990a; Lindberg et al., 1984; Slater & Terry, 1987; Stouffer & Tyler, 1990a, 1990b). Of particular interest is the Iowa Tinnitus Handicap Questionnaire (Appendix I) which is used to identify specific areas of handicap and to monitor a patient's progress with particular treatment programs (Kuk et al., 1990). The development of this questionnaire consisted of two phases. Phase I involved the administration of 87 questions to 100 tinnitus patients. From their responses, 59 items were eliminated due to redundancy or insensitivity to differences among subjects. Redundancy was determined by examining the correlation coefficients among items combined within each subscale. Insensitivity was determined by assigning a frequency count of the proportion of time a specific rating was assigned to each item.Items assigned a 0 or 100 50% of the time were deemed insensitive. Phase II consisted of administering the 27 remaining questions to 319 patients. A factor analysis of the patients' responses

revealed a three-factor structure. Factor one examined the emotional, physical and social consequences of tinnitus. Factor two looked at the hearing ability of the patient. Finally, factor three involved the patient's view of their tinnitus. The questionnaire displayed high internal consistency reliability (Cronbach's alpha = 0.94), and validity as reflected by correlations with satisfaction and depression scales. The Iowa Tinnitus Handicap Questionnaire was developed in an attempt to standardize measures used to validate the efficiency of different treatment approaches.

A second questionnaire, The Tinnitus Questionnaire (Appendix II), contains questions designed to obtain data on patient reactions to their tinnitus (Stouffer & Tyler, 1990a). The responses are meant to generate data concerning population characteristics, perceptual characteristics, the impact of tinnitus on daily life, and etiology.

There exists no medical or surgical cure for tinnitus (House & Brackman, 1981). Various surgical techniques have been attempted over the years including excising the main trunk of the vestibular nerve and sectioning of the cochlear nerve (Fisch, 1970). Results to date have been unpredictable and success rates low. Many available medications used for the reduction or elimination of tinnitus symptoms have severe limitations and/or side effects (Brown et al., 1981, Goodey, 1987; Murai, Tyler, Harker & Stouffer, 1992). Intravenous lignocaine is the only pharmacological treatment known to greatly reduce or abolish tinnitus in a high percentage of patients (Melding & Goodey, 1979). However, the effect lasts only a few minutes or hours.

Biofeedback techniques have also been utilized in the management of tinnitus. Biofeedback is designed to give the client conscious control over a physiological variable

of which s/he has had no previous conscious control. This strategy does not decrease the severity of the tinnitus but rather, teaches the patient to relax and tolerate the tinnitus to a greater extent. Carmen and Svihovec (1984) found a significant correlation between tinnitus and tension levels as reported on self-rating scales.

Many foods and drugs have been reported to cause or aggravate tinnitus. Withdrawing these causal agents would presumably result in eliminating or alleviating tinnitus symptoms. Such agents reported include aspirin, quinine, coffee, tea, red wine, tonic water, cheese, and chocolate (Goodey, 1981). These claims have not been substantiated with experimental evidence to date.

It has long been reported by hearing-impaired individuals that their tinnitus could be diminished by wearing a hearing aid (Saltzman & Ersner, 1947). It is assumed that the amplified sound may mask the patient's tinnitus.

Another promising technique used to alleviate tinnitus is electrical stimulation. Politzer (1953) first noted a relief of tinnitus when direct current was applied to the ear of one of his patients. Studies to date have met with some success (House, 1984). However, there is some evidence that long term electrical stimulation damages tissue, particularly neural tissue (Aran, 1977).

Counselling should be incorporated in some fashion with all forms of tinnitus management. Individuals with tinnitus need information regarding what is known and what is not known about tinnitus. They need to know that their tinnitus is not life threatening and that tinnitus is not normally an indication that their hearing sensitivity will decrease (Sheldrake, Wood & Cooper, 1985). It is important to realize that tinnitus

can create a psychological problem or can elevate an existing problem.

Habituation and desensitization are two new tinnitus treatments that are based on psychological behaviour modification techniques. Habituation is essentially a decrease in a response to a stimulus after repeated exposures. It differs from adaptation which is a decrease in information from the sensory system. Jastreboff and Hazell (1993) proposed the use of habituation for tinnitus treatment, and early results are promising. Systematic desensitization is aimed at treating people with maladaptive anxiety (Wolpe, 1961). It involves repeated exposure to an aversive stimulus which is then paired with a pleasant experience (eg. relaxation). More research is required to determine the validity of this method.

Tinnitus maskers are portable noise generators that produce either wide band or narrow band spectrum noise. The development of the tinnitus masker resulted from work conducted by Vernon (1975). Tinnitus maskers are available as separate masking units or as combination devices containing a hearing aid. The volume of the masker is controlled by the user. Thus, when fitting masking devices, it is important to remember that they are capable of generating sufficiently loud sounds to damage hearing. Therefore, over-amplification should always be avoided when fitting the device.

Tinnitus sufferers may get active or passive relief as a result of wearing a tinnitus masker. Active relief is obtained when the device is worn. The masking sound "covers" the tinnitus and is deemed more "tolerable" than the tinnitus. Vernon and Schleuning (1978) suggested that tinnitus sufferers find the masking noise to be more pleasant than their tinnitus for a number of reasons. First, the band of noise generated by the tinnitus

masker is more pleasant than the tinnitus signal which is generally high frequency. Second, the masking noise is external and can be ignored more easily than an internally generated sound. It is worth mentioning that much of this reasoning is based on anecdotal evidence. Roeser and Price (1980) report that their clinical experience did not support the idea that the masking signal is typically more tolerable than the patient's own tinnitus.

Passive relief may occur after the masker is removed. Josephson (1931) first observed what is now referred to as residual inhibition. In some patients, when the tinnitus masker is turned off, tinnitus is decreased or absent for a variable period of time. The physiological mechanisms responsible for residual inhibition are not known.

Several studies suggest that tinnitus maskers may provide effective tinnitus relief, but the number of patients who benefit from tinnitus maskers is unclear (Erlandsson, Ringdahl, Hutchins &Carlsson, 1987; Hazell et al., 1985; Roeser & Price, 1980; Tyler & Bentler, 1987; Vernon, 1981). Vernon and Scheuning (1978) stated that 81% of 32 patients had obtained complete relief from their tinnitus as a result of using maskers. No follow-up data were reported. In contrast, Roeser and Price (1980) reported that only 26% of 34 patients obtained some benefit from maskers. Additionally, they stated that it was their clinical opinion that amplification was overall more accepted than maskers in relieving tinnitus.

Information is limited regarding the use and effectiveness of tinnitus maskers. For example, do patients wear maskers for a short period of time and then discard them as ineffective, or do tinnitus maskers provide long-term relief for tinnitus sufferers? Physicians and audiologists are often unable to decide whether to treat tinnitus with a

masker.

The current investigation attempted to evaluate the effectiveness of tinnitus maskers through the comparison of tinnitus maskers and placebo devices. If maskers were found to be effective with some patients, we would be better able to determine which patients could potentially benefit from tinnitus maskers. Additionally, we would be better able to counsel patients regarding realistic expectations from the use of tinnitus maskers by determining the effect maskers have on tinnitus loudness, annoyance, severity, and other tinnitus parameters. If tinnitus maskers were found to be ineffective in the treatment of tinnitus, research should be directed towards other methods of treatment.

METHODS

Subjects

Subjects for this study were recruited from tinnitus populations seen at the Speech and Hearing Clinic of the Department of Communicative Disorders, Elborn College and St. Joseph's Hospital, both in London, Ontario. Also, advertisements were placed in Tinnitus Times, a publication produced by the Canadian Hearing Society, the Newsletter of the Canadian Tinnitus Association, and The Pennysaver magazine. Subject participation in this study was completely voluntary.

To qualify for the study, only patients with tinnitus present 80% of the time who did not wear a hearing aid were asked to participate. Initial respondents (n=23), after agreeing to participate in the study, were provided with information describing the proposed research and expectations of their involvement (Appendix III). It was made clear to the subjects that they were free to withdraw from the study at any time. All subjects were asked if they had ever seen an Otolaryngologist in relation to their tinnitus. All subjects responded that they had.

Prior to participating in the study, it was necessary to determine if the subject's tinnitus was maskable. Maskability was determined using both unilateral and bilateral masking techniques. Using a narrow band external noise stimulus, the intensity level of the stimulus was increased slowly until the subject reported that they could hear only the external noise and not their tinnitus. Each ear was individually masked, and in addition, bilateral masking of tinnitus was evaluated. Each condition was repeated three times and the average HL at which masking occurred was calculated. If the subject's tinnitus was

not masked at a level of 90 dB HL, the ascending masking trial was stopped. If consistent masking was not possible for the three conditions, the subject's tinnitus was deemed unmaskable and s/he did not participate in the study. If a subject's tinnitus could not be masked utilizing a narrow band of masking that approximated a tinnitus masker, it was considered unlikely that a tinnitus masker would be of any benefit. On the basis of these measurements, 3 subjects were excluded from the study. Sixteen males and 4 females between the ages of 41 and 68 were selected to participate in the study, yielding a sample of 20 (M age = 52.44, SD age = 7.99).

Stimuli and equipment

Threshold and psychophysical testing was conducted using either a Grason-Stadler GSI-16 audiometer or a Grason-Stadler GSI-10 audiometer. Insert earphones (Etymotic ER-3A) were used as the transducer. All threshold and experimental testing was conducted in a double-walled audiometric sound room (IAC).

The tinnitus masker used in the study was a Viennetone Behind-the-Ear (BTE) AM/Ti tinnitus masker. Specifications for the device are provided in Appendix IV. The placebo device was identical to the tinnitus masker but was non-functional.

General Procedure

Subjects were asked to complete The Iowa Tinnitus Handicap Questionnaire (Appendix I) and the Tinnitus Questionnaire (Appendix II). The Iowa Tinnitus Questionnaire (Kuk et al., 1990) is a 27-item questionnaire consisting of three subtests. Subtest one is designed to reflect the physical, emotional, and social consequences of tinnitus. Subtest two is designed to reflect the hearing ability of the patient. Subtest three

is designed to reflect the patients' view of tinnitus. Subtests can be considered individually or scores can be combined into a total score for the questionnaire. Patients are instructed to write a number between "0" and "100" beside each item to represent how much they agreed with the item. A 0 was assigned if they strongly disagreed with the item, and a 100 if they strongly agreed with the item. The Tinnitus Questionnaire (Stouffer & Tyler, 1990a) is an unstandardized questionnaire consisting of ten questions. It is designed to determine the effect of tinnitus on loudness, severity, and other parameters. Upon completion of the two questionnaires, puretone air conduction hearing thresholds were obtained using standard audiometric techniques. Threshold testing was conducted at all octave and inter-octave frequencies between 250 and 8000 Hz. Speech reception thresholds were obtained and word discrimination abilities were assessed for each subject.

Upon completion of audiometric testing, the following techniques were used to quantify the subject's tinnitus psychophysically:

1) Matching of tinnitus loudness to a 500 Hz puretone,
2) Unilateral and bilateral masking of tinnitus using narrow band noise at 2000 and 4000 Hz, and
3) Measurement of residual inhibition from unilateral and bilateral masking of tinnitus using a 4000 Hz narrow band noise presented for one minute at 10 dB above the tinnitus masking level.

For subjects qualifying and agreeing to participate in the study, impressions of their ears were made in order to make personal earmolds. Ten subjects were randomly

assigned to receive a tinnitus masker in the ear with tinnitus. If tinnitus was present bilaterally, the masker was worn on the ear in which the tinnitus was perceived as being loudest. The remaining 10 subjects were assigned to a reverse treatment order. This group was fitted with an instrument identical in appearance to the tinnitus masker but which was a non-functioning instrument. Instruments were made non-functional by the manufacturer. The subjects were told that the device was a non-audible tinnitus masker. If they questioned the investigators further, they were informed that the device delivers an ultra-high frequency signal that is non-audible to humans. After a six week period, subjects were fitted with the alternative devices. That is, the subjects wearing the tinnitus maskers were fitted with placebos and vice versa.

During the pre-test, subjects were given a booklet and asked to keep a daily record of the time they wore the tinnitus masker or placebo device daily (Appendix V). Additionally, they were given weekly questionnaires to complete (Appendix VI), designed to keep track of their tinnitus and success with each device as well as to encourage subjects to continue participating fully in the study. The researchers recognize that calling attention to the subjects' tinnitus might influence their responses. However, the influence, if any, was assumed to be equivalent for the masker and placebo treatments. Patients were contacted biweekly by telephone to encourage them to wear the device as much as was practical. In addition, patients were given full instructions regarding the use and maintenance of the tinnitus masker or placebo device before their initial use. Training was repeated when subjects changed from a placebo to a tinnitus masker and vice versa. Tinnitus masker success was determined primarily through

subject responses on the Iowa Tinnitus Handicap Questionnaire. This measure, as well as the Tinnitus Questionnaire, was made before tinnitus masker/placebo devices were fitted and after each had been worn for a six week period.

Threshold information was obtained after the first six week interval. It was important to monitor the subjects' hearing threshold levels as some subjects suffered from Meniere's disease. Meniere's disease is characterized by tinnitus, severe vertigo and fluctuating hearing loss. Consequently, threshold measures were taken for all subjects prior to receiving the second device.

Two subjects did not complete the study. The first subject, a male, did not feel that he was receiving benefit from the tinnitus masker and did not wish to complete the last six weeks of the trial. The other participant, a female, did not complete the study due to personal reasons. Both subjects began the study with the tinnitus masker and dropped out after the first six weeks without wearing the inaudible placebo device. Therefore, 18 subjects in total completed the study. Eight received the tinnitus masker first, followed by the placebo. The remaining 10 subjects received the devices in the reverse order.

Upon completion of the study, participants were informed of the nature of the study. They were told that it involved a placebo. Information was provided to all participants regarding the results of the study as well as other related research in the area of tinnitus management.

RESULTS

Iowa Tinnitus Handicap Questionnaire

A 2X3 split-plot analysis of variance (ANOVA) was conducted on each of subtest 1, 2, 3, and total score to evaluate whether statistical differences existed for sex (male/female) and condition (pretest/masker/placebo). Additional 2X3 split-plot ANOVAs were conducted for each of subtests 1, 2, 3, and total score to determine if statistical differences existed between order of presentation (masker first/placebo first) and condition. Finally, 2X3 split-plot ANOVAs were conducted for each of the subtests and the total score to determine if differences existed between subjects who suspected the "high frequency" device was a placebo and subjects who did not and condition. No significant interactions or main effects were found for any of the ANOVAs conducted.

To determine whether the scores on subtest 1, 2, 3 or total scores differed between the pretest, the masker and the placebo conditions, a series of repeated measures ANOVA designs were performed. Each device was worn for a period of six weeks. Mauchley's sphericity test was conducted for each analysis and was found to be non-significant. Therefore, the assumption of sphericity was not violated. An alpha of 0.10 was used in order to increase power. No error rate control was employed. No significant differences were found between conditions for subtest 1, subtest 3, and total score. Using an alpha of 0.10, a significant difference between conditions was found for scores on subtest 2 ($\underline{F}\,(1, 24) = 3.60$, $\underline{p} < 0.10$), with mean scores following the masker condition being highest. Mean scores and 95% confidence intervals for each condition are plotted in Figures 1, 2 and 3 for subtests 1, 2 and 3 respectively. Figure 4 illustrates

mean scores and 95% confidence intervals for the total score.

Tinnitus Questionnaire

One 2X3 split-plot ANOVAs was performed on each of questions 3 to 10 to evaluate whether statistical differences existed for sex (male/female) and condition, for order (masker first/placebo first) and condition, and for subjects who suspected the "high frequency" device was a placebo and subjects who did not and condition. Questions one and two were not analyzed because the answers to these questions were expected to remain the same across conditions. No significant interactions or main effects were found.

Figures 5 to 12 summarize mean scores and 95% confidence intervals for questions 3 to 10 of the Tinnitus Questionnaire obtained during the pretest, after the masker was worn for six weeks, and after the placebo was worn for six weeks. The assumption of sphericity was not violated for any of the analyses performed. No significant differences were found between conditions for any question.

No error rate control was used, resulting in "liberal" tests. Therefore, the possibility of making type II error was minimal.

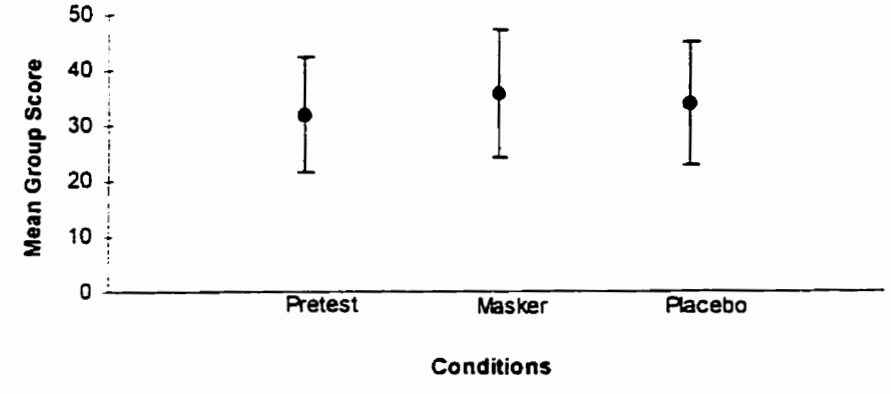

Figure 1: This is a graphical representation of the mean group scores for subtest one (physical, emotional, and social consequences of tinnitus) of the Iowa Tinnitus Handicap Questionnaire. Error bars indicate 95% confidence intervals.

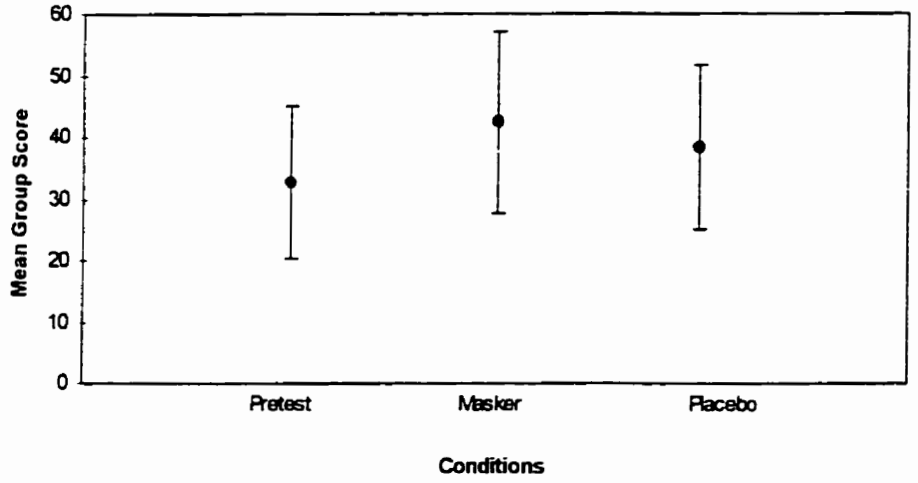

Figure 2: This is a graphical representation of the mean group scores for subtest two (hearing ability of the patient) of the Iowa Tinnitus Handicap Questionnaire. Error bars indicate 95% confidence intervals.

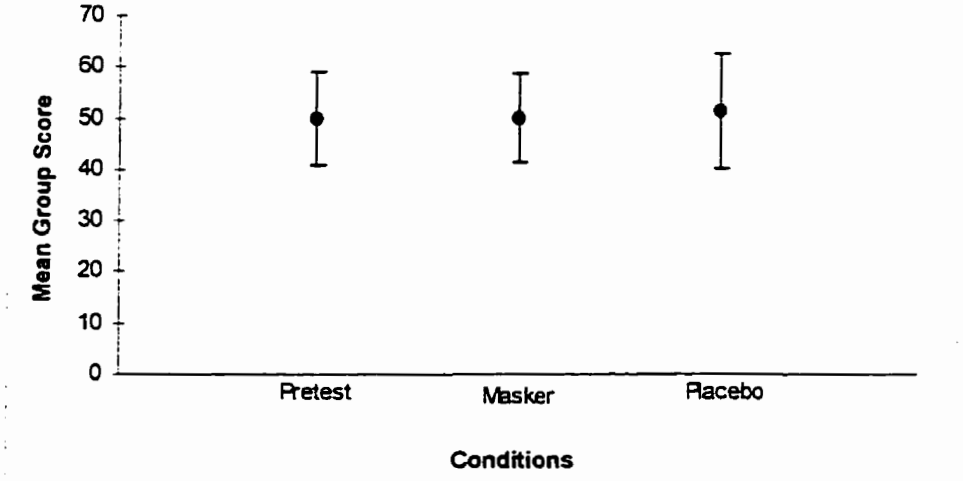

Figure 3: This is a graphical representation of the mean group scores for subtest three (patient's view of their tinnitus) of the Iowa Tinnitus Handicap Questionnaire. Error bars indicate 95% confidence intervals.

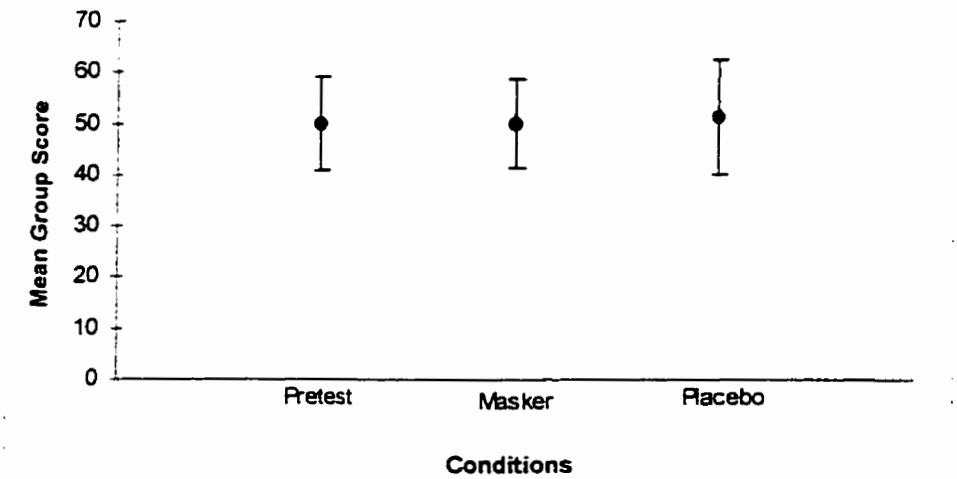

Figure 4: This is a graphical representation of the mean group scores for the total score of the Iowa Tinnitus Handicap Questionnaire. Error bars indicate 95% confidence intervals.

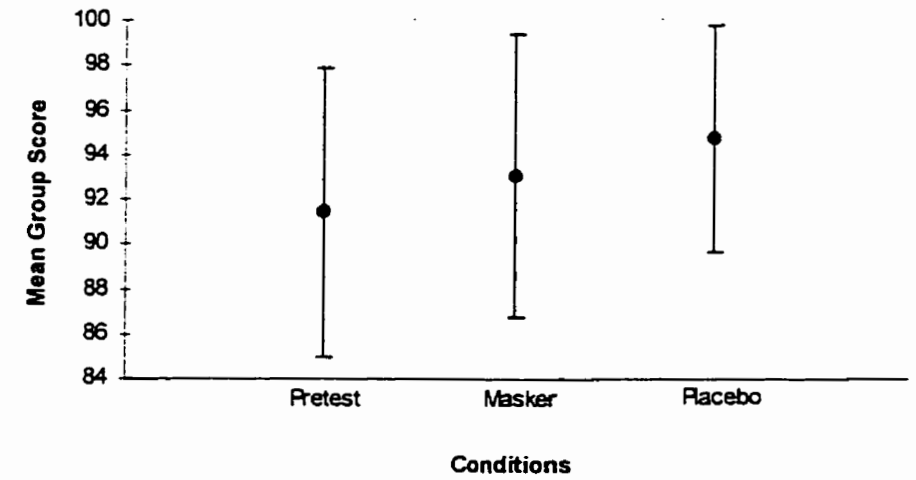

Figure 5: This is a graphical representation of the mean group scores for question three of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

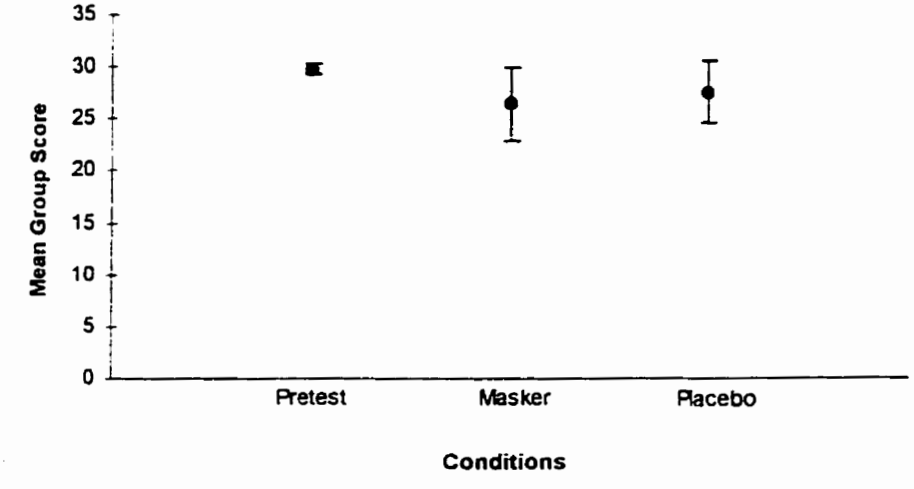

Figure 6: This is a graphical representation of the mean group scores for question four of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

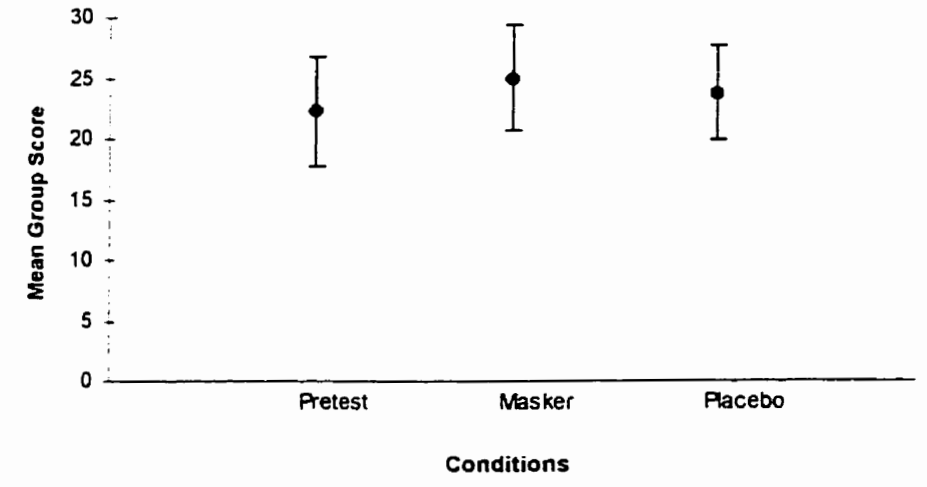

Figure 7: This is a graphical representation of the mean group scores for question five of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

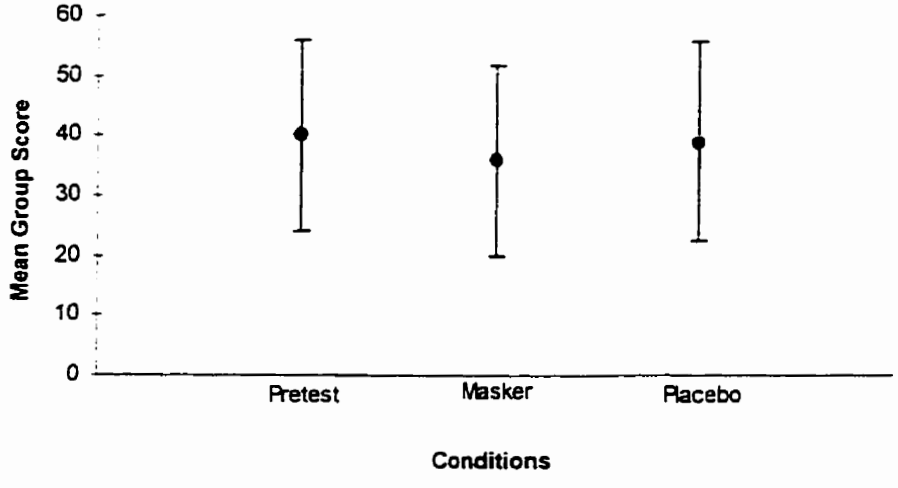

Figure 8: This is a graphical representation of the mean group scores for question six of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

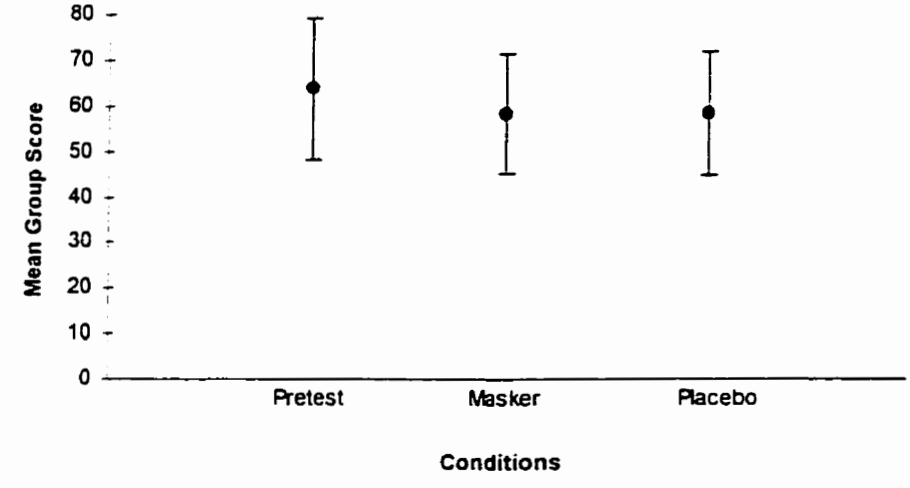

Figure 9: This is a graphical representation of the mean group scores for question seven of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

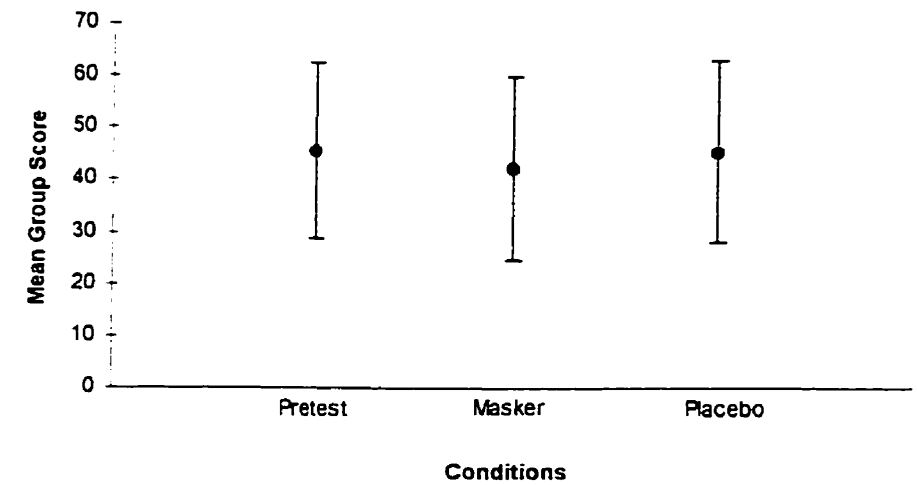

Figure 10: This is a graphical representation of the mean group scores for question eight of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

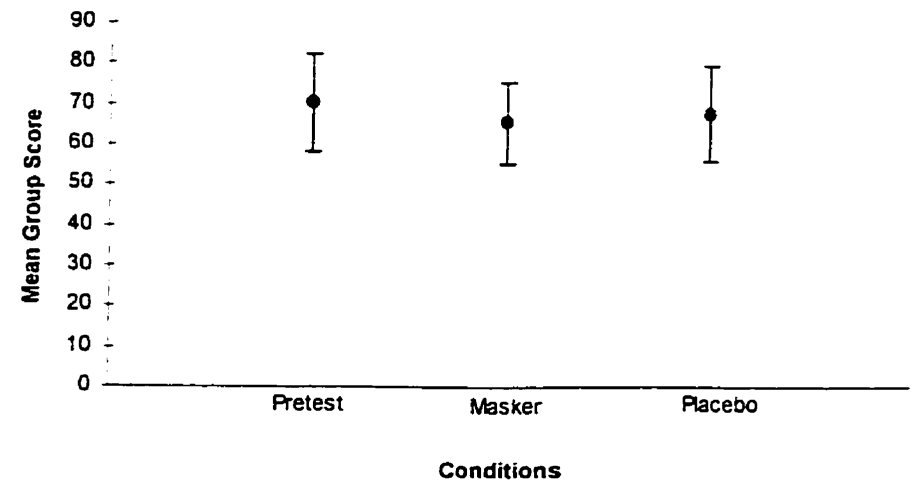

Figure 11: This is a graphical representation of the mean group scores for question nine of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

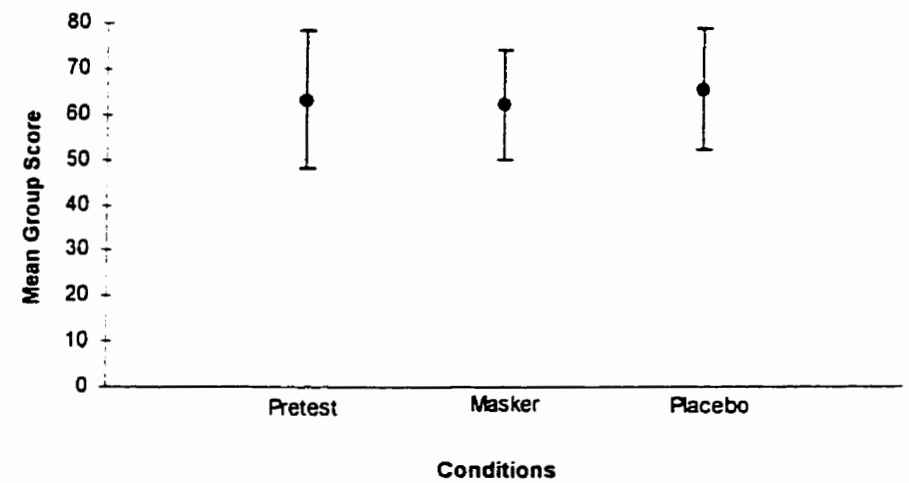

Figure 12: This is a graphical representation of the mean group scores for question ten of the Tinnitus Questionnaire. Error bars indicate 95% confidence intervals.

DISCUSSION

The current investigation found a significant difference only between scores on subtest 2 of the Iowa Tinnitus Handicap Questionnaire (Appendix I) across the pretest condition, the masker condition and the placebo condition. No other significant differences were found. Due to the fact that no error control was utilized, the significant differences found in subtest 2 are likely to be spurious and due to chance. These results are not consistent with previous results examining the efficacy of masker treatment in alleviating tinnitus.

Patients frequently visit an audiological clinic because they are concerned about hearing loss, tinnitus or both. Stouffer and Tyler (1990) studied patients with both hearing loss and tinnitus seen at an audiology-otology clinic. Thirty-eight percent of the patients reported hearing loss as their primary concern and 48% reported tinnitus as their primary concern. That is, patients with both hearing loss and tinnitus more often report that they are more worried about tinnitus. Axelsson and Ringdahl (1989) revealed that of 186 patients who suffered from tinnitus 'often', 53% 'would like treatment' and 5.6% considered 'treatment urgent'. Of those suffering from tinnitus 'always', 32% 'would like treatment' and 25% considered 'treatment urgent'. Lindberg et al. (1984) reported that 83% of tinnitus patients questioned were interested in obtaining treatment. It is apparent from these studies that tinnitus poses a significant concern and successful attempts to treat it are needed.

Tinnitus maskers are currently used as one form of treatment for tinnitus patients. They have been used in the treatment of tinnitus for approximately 20 years, yet it

remains unclear how many individuals derive benefit from tinnitus maskers. Previous attempts to determine the success of tinnitus maskers have provided variable results. Vernon and Schleuning (1978) strongly recommended the use of tinnitus maskers based on their own clinical experience. They stated that 81% of patients treated with tinnitus maskers showed complete relief of their tinnitus. However, no follow-up data were provided for this study. The data used by Vernon and Schleuning (1978) were obtained during tinnitus evaluations to predict successful use. Roeser and Price (1980) reported that 26% of the patients in their study showed at least some benefit from a tinnitus masker as measured using a semi-structured unstandardized questionnaire. Schleuning, Johnson and Vernon (1980) examined 105 patients and reported that 68% showed partial relief using a tinnitus masker and 15% demonstrated complete relief. This particular study did not utilize a well-defined fitting strategy. Success was determined through the use of a non-standardized questionnaire. The total time a masker was worn was not specified. Hazell et al. (1985) performed a study involving three separate centres in Britain. All three centres used different selection criteria for participants. Across all centres, 79% of participants reported partial or complete success with a tinnitus masker using a six month unstandardized questionnaire as a success/fail criterion. However, one centre published an independent report (Stephens & Corcoran, 1985) which did not agree with the larger report. They reported that for patients with tinnitus and no degree of hearing loss, there were no significant differences between patients who used a tinnitus masker and a control group of patients who received only counselling. For patients with tinnitus and a hearing loss, "no dramatic differences were obtained" (Stephens &

Corcoran, 1985). It is suggested that there is likely a strong placebo effect. That is, those patients who received tinnitus maskers were likely to benefit from the counselling and increased attention regardless of whether or not the masker was successful in alleviating their tinnitus.

It is evident that previous research conducted in the area of tinnitus masker treatment efficacy has had very little documented success. Much of the data collected have been anecdotal with little or no objective data to support it. It is important to recognize the definition of the patient group selected, the techniques used to fit the devices and the definition of success used when evaluating the benefit from using a tinnitus masker. Selection and success criteria must be clearly defined. To date, most research evaluating the benefit from using a tinnitus masker has not defined selection or success criteria. Research must be carried out systematically and in a controlled fashion.

The current investigation utilized the Iowa Tinnitus Handicap Questionnaire (Appendix A) as its primary tool for determining tinnitus masker success. It is one of the few measures that can reliably quantify the severity of handicap experienced by a tinnitus patient. By using such a measure, we have ensured uniform comparison among studies that also choose to use the Questionnaire to determine success of treatment, even if different treatments are examined. The usefulness of a test depends on its validity and reliability. The Iowa Tinnitus Handicap Questionnaire has high internal consistency reliability (Cronbach's alpha = 0.94) and validity (as reflected by correlates with life satisfaction and depression scales).

It is difficult to quantify tinnitus. However, every attempt must be made to control for factors that can be controlled. This area needs to be examined more closely. Standardization of measures to validate the efficacy of different treatment approaches must be encouraged. Our study controlled for the time of masker use as well as participant selection criteria. Subjects wore the masker or placebo at least 3 hours per day up to 15 hours per day ($\underline{M}$ = 8.01, $\underline{SD}$ = 5.00). Thus, if tinnitus maskers are effective, they should have been effective under the experimental conditions of this study. A standardized questionnaire was used to determine success or failure with the device. We did not rely on anecdotal evidence.

Perhaps bilateral tinnitus maskers should have been evaluated, even for patients with unilateral tinnitus. However, Tyler and Conrad-Armes (1983) noted that, in many patients, the SPL of a masker required to mask tinnitus was similar in either ear, even if tinnitus was unilateral. This suggests that tinnitus masking occurs centrally. Individuals reporting unilateral tinnitus often report that the perception of tinnitus shifts to the opposite ear when unilateral masking is applied. Tinnitus masking suggests that tinnitus can occur either centrally or peripherally or perhaps both.

Tinnitus sufferers were not found to benefit from the tinnitus masker used in our study. Counselling must continue to play an essential role in helping these individuals cope with tinnitus. It is essential to provide patients with information regarding tinnitus as well as inform them that it is benign when underlying pathology has been ruled out. We must now turn our attention towards new treatment solutions and continue with objective, controlled research.

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APPENDIX I

Iowa Tinnitus Handicap Questionnaire

Place a number between 0 and 100 in the blank space preceding each statement to represent how much you disagree or agree with each statement.
0 indicates you strongly disagreed with the statement.
100 indicates you strongly agree with the statement.

____ 1. I do not enjoy life because of tinnitus.
____ 2. My tinnitus has gotten worse over the years.
____ 3. Tinnitus interferes with my ability to tell where sounds are coming from.
____ 4. I am unable to follow a conversation during meetings because of tinnitus.
____ 5. Tinnitus causes me to avoid noisy situations.
____ 6. Tinnitus interferes with my speech understanding when talking with someone in a noisy room.
____ 7. I feel uneasy in social situations because of tinnitus.
____ 8. The general public does not know about the devastating nature of tinnitus.
____ 9. I cannot concentrate because of tinnitus.
____ 10. Tinnitus creates family problems.
____ 11. Tinnitus causes me to feel depressed.
____ 12. I find it difficult to explain what tinnitus is to others.
____ 13. Tinnitus causes stress.
____ 14. I am unable to relax because of tinnitus.
____ 15. I complain more because of tinnitus.
____ 16. I have trouble falling asleep at night because of tinnitus.
____ 17. Tinnitus makes me feel tired.
____ 18. Tinnitus makes me feel insecure.
____ 19. Tinnitus contributes to a feeling of general ill health.
____ 20. Tinnitus affects the quality of my relationships.
____ 21. Tinnitus has caused a reduction in my speech understanding ability.
____ 22. Tinnitus makes me feel annoyed.
____ 23. Tinnitus interferes with my speech understanding when listening to the television.
____ 24. Tinnitus makes me feel anxious.
____ 25. I think I have a healthy outlook on tinnitus.
____ 26. I have support from my friends regarding my tinnitus.
____ 27. I feel frustrated frequently because of tinnitus.

APPENDIX II

Tinnitus Questionnaire

Identification Number _____

Circle one of the following: Male Female

Indicate your birthdate: Day _____ Month _____ Year _____.

1. How many years have you had tinnitus? _____ Years.
2. How many years has your tinnitus **bothered** you? _____ Years.
3. During the time you are awake, what percentage of the time is your tinnitus present. For example, 25% indicates that tinnitus is there one-quarter of the time. _____ % Indicate with a number between 0 and 100.
4. How many days per month is your tinnitus present?
   _____ Days per month (maximum = 30)
5. How many days per month are you **bothered** by tinnitus?
   _____ Days per month (maximum = 30)
6. What percentage of the time does your tinnitus interfere in your daily life? For example, 100% indicates that tinnitus always interferes in your daily life.
   _____ % Indicate with a number between 0 and 100.
7. Use a number between 0 and 100 to indicate how ANNOYING you find your tinnitus - 0 indicates it is not annoying, 100 indicates it is extremely annoying.
   _____ % Write a number between 0 and 100.
8. Use a number between 0 and 100 to indicate interference with CONCENTRATION because of your tinnitus - 0 indicates no interference with concentration, 100 indicates complete interference with concentration.
   _____ % Write a number between 0 and 100.
9. Use a number between 0 and 100 to indicate the LOUDNESS of your tinnitus - 0 indicates you no longer hear it, 100 indicates it is extremely loud.
   _____ % Write a number between 0 and 100.
10. Use a number between 0 and 100 to indicate the SEVERITY of your tinnitus - 0 indicates a lack of severity, 100 indicates it is extremely severe.
    _____ % Write a number between 0 and 100.

APPENDIX III

AN EVALUATION OF TINNITUS MASKER EFFECTIVENESS

Information Summary

This study will investigate the success of two different types of tinnitus maskers in reducing tinnitus annoyance. If you agree to participate, you will be asked to complete two questionnaires. You will also listen to several sounds and judge whether they are as loud as your tinnitus or report if the sound blocks out your tinnitus. This study will last three months. During this time you will make four trips to the University of Western Ontario in London. For each trip you will spend about an hour at our clinic. During the study you will also wear two tinnitus maskers and decide if they are effective in reducing tinnitus. One masker will be worn at a time. Each masker will be worn for six weeks. The study may enable us to measure the usefulness of tinnitus maskers. You will be identified by a number to ensure confidentiality. Your participation in this study is voluntary and you may decide not to participate at any time during the study. If you have further questions about the study, call Dr. James Stouffer and (519)661-2111 X 8214.

APPENDIX IV

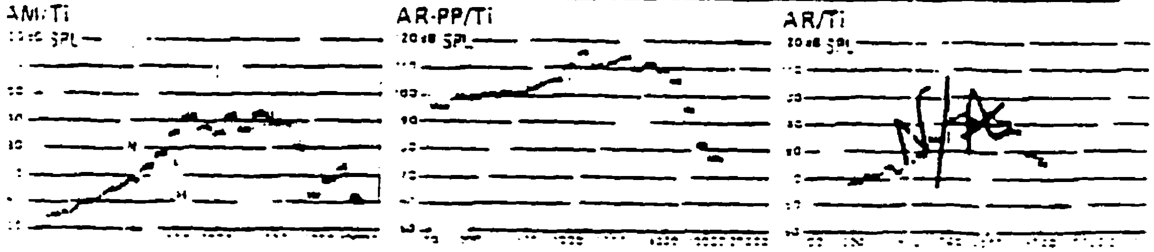
Technical Specifications

	AM/Ti	AR-PP/Ti	AR/Ti
Dimensions:	max. length 23 mm (1.55") max. thickness 10 mm (0.40")	max. length 30 mm (1.13") max. thickness 8.5 mm (0.33")	max. length 30 mm (1.13") max. thickness 8.5 mm (0.33")
Weight:	4.8 g (0.17 oz) approx. 7.5 g (0.26 oz) including battery	3.5 g (0.123 oz) approx. 4.5 g (0.16 oz) including battery	3.5 g (0.123 oz) approx. 4.5 g (0.16 oz) including battery
Amplifier:	4 Silicon transistors, easy serviceable printed circuit, tone control switch (bass cut), switch O-M	4 Silicon transistors + integrated circuit output stage, printed circuit, on/off switch	4 silicon transistors, easy serviceable printed circuit [illegible]
Receiver:	magnetic wide-range type, shielded, supported by rubber boot	magnetic wide-range type, shielded, supported by rubber boot	magnetic wide-range type, shielded, supported by rubber boot
Battery:	Zinc Air cell (Activair) 1.4 V A 675 or equiv. .... approx. 400 hrs. Mercury cell 1.4 V 675 P or equiv. .... approx. 200 hrs.	A 13 or equiv. .... approx. 100 hrs. RM 13 or equiv. .... approx. 50 hrs.	A 13 or equiv. .... approx. [illegible] hrs. RM 13 or equiv. .... approx. [illegible] hrs.
Current drain:	1 mA±0.1 mA (at 1.35 V)	1 mA±0.15 mA (at 1.35 V, zero signal)	0.7 mA±0.1 mA (at 1.35 V)

Handwritten across the AR/Ti column: "Not Available"

	AM/Ti dB Noise level 2 cm³ Tone N	AM/Ti dB Noise level 2 cm³ Tone H	AM/Ti dB Noise level Zwislocki Tone N	AM/Ti dB Noise level Zwislocki Tone H	AR-PP/Ti dB Noise level 2 cm³	AR-PP/Ti dB Noise level Zwislocki	AR/Ti dB Noise level 2 cm³	AR/Ti dB Noise level Zwislocki
HAIC	74	51	79	55	105	109	[illegible]	[illegible]
1000 Hz, 1/3 Oct. filter	78	57	85	72	109	113	55	[illegible]
Peak	83	82	93	80	115	117	50	55
Wide range	53	57	88	94	113	122	35	[illegible]
Frequency range HAIC/arm Y 40 dB	150–9,000 Hz	450–10,000 Hz	350–8,000 Hz	500–9,000 Hz	120–7,000 Hz	130–8,000 Hz	230–5,000 Hz	400–5,500 Hz

AM/Ti AR-PP/Ti AR/Ti



APPENDIX V

TINNITUS MASKER RESEARCH DAILY LOG

WEEK OF_____ ID #_____

	MON	TUES	WED	THURS	FRI	SAT	SUN
7-8 am							
8-9 am							
9-10 am							
10-11 am							
11-12 pm							
12-1 pm							
1-2 pm							
2-3 pm							
3-4 pm							
4-5 pm							
5-6 pm							
6-7 pm							
7-8 pm							
8-9 pm							
9-10 pm							
10-11 pm							
11-12 am							
12-1 am							
1-2 am							
2-3 am							
3-4 am							
4-5 am							
5-6 am							
6-7 am							

Weekly Tinnitus Questionnaire

Identification Number _____

1. During the time you are awake, what percentage of the time is your tinnitus present? For example, 25% indicates that the tinnitus is there one-quarter of the time.

   _____ % Indicate with a number between 0 and 100.

2. How many days per week is your tinnitus present?

   _____ Days per week (maximum = 7)

3. How many days per week are you **bothered** by tinnitus?

   _____ Days per week (maximum = 7)

4. What percentage of the time does your tinnitus interfere in your daily life? For example, 100% indicates that tinnitus always interferes in your daily life.

   _____ % Indicate with a number between 0 and 100.

5. Use a number between 0 and 100 to indicate how ANNOYING you find your tinnitus - 0 indicates it is not annoying, 100 indicates it is extremely annoying.

   _____ % Write a number between 0 and 100.

6. Use a number between 0 and 100 to indicate interference with CONCENTRATION because of your tinnitus - 0 indicates no interference with concentration, 100 indicates complete interference with concentration.

   _____ % Write a number between 0 and 100.

7. Use a number between 0 and 100 to indicate the LOUDNESS of your tinnitus - 0 indicates you no longer hear it, 100 indicates it is extremely loud.

   _____ % Write a number between 0 and 100.

8. Use a number between 0 and 100 to indicate the SEVERITY of your tinnitus - 0 indicates a lack of severity, 100 indicates it is extremely severe.

   _____ % Write a number between 0 and 100.

APPENDIX VII

CONSENT FORM

AN EVALUATION OF TINNITUS MASKER EFFECTIVENESS

I have read the attached letter of information for the tinnitus masker study and all questions have been answered to my satisfaction. I hereby agree to participate.

_____ _____

Date Signature

APPENDIX VIII

Ethics Approval

REVIEW BOARD FOR HEALTH SCIENCES RESEARCH INVOLVING HUMAN SUBJECTS

1989-90 CERTIFICATION OF APPROVAL OF HUMAN RESEARCH

ALL HEALTH SCIENCES RESEARCH INVOLVING HUMAN SUBJECTS AT THE UNIVERSITY OF WESTERN ONTARIO IS CARRIED OUT IN COMPLIANCE WITH THE MEDICAL RESEARCH COUNCIL OF CANADA "GUIDELINES ON RESEARCH INVOLVING HUMAN SUBJECT".

1989-90 REVIEW BOARD MEMBERSHIP

1) B. Borwein. Associate Dean - Research - Medicine (Chairman) (Anatomy, Ophthalmol.)
2) S. Hoddinott. Assistant Director of Research Services (Epidemiology)
3) A. Webster. St. Joseph's Hospital Representative (Anaesthesia)
4) D. Moulin. Victoria Hospital Representative (Clinical Neurological Sciences)
5) D. Bocking. University Hospital Representative (Physician - Internal Medicine)
6) C. Seligman. Office of the President Representative (Psychology)
7) E. Jones. Office of the President Representative (Community)
8) G. Dickinson. Office of the President Representative (Legal)
9) D. Freeman. Faculty of Medicine Representative (Medicine)
10) J. Koval. Faculty of Medicine Representative (Epidemiology & Biostatistics)
11) G. Pringle. Faculty of Dentistry Representative (Pathology)
12) S. Faux. Faculty of Nursing Representative (Nursing)
13) A.S. Yoviech. Faculty of Applied Health Sciences Representative (Com. Disorders)
14) G. Leyshon. Faculty of Physical Education Representative (Physical Education)
15) G. Chance. Research Institutes Representative (Paediatrics)
Alternates are appointed for each member.

THE REVIEW BOARD HAS EXAMINED THE RESEARCH PROJECT ENTITLED:
"An evaluation of Tinnitus Masker effectiveness."

REVIEW NO: 2546E

AS SUBMITTED BY: Dr. J.L. Stouffer. Communicative Disorders. EC

AND CONSIDERS IT TO BE ACCEPTABLE ON ETHICAL GROUNDS FOR RESEARCH INVOLVING HUMAN SUBJECTS UNDER CONDITIONS OF THE UNIVERSITY'S POLICY ON RESEARCH INVOLVING HUMAN SUBJECTS

APPROVAL DATE: 23 May 1990

AGENCY: HEALTH RESEARCH & DEVELOPMENT GRANTS

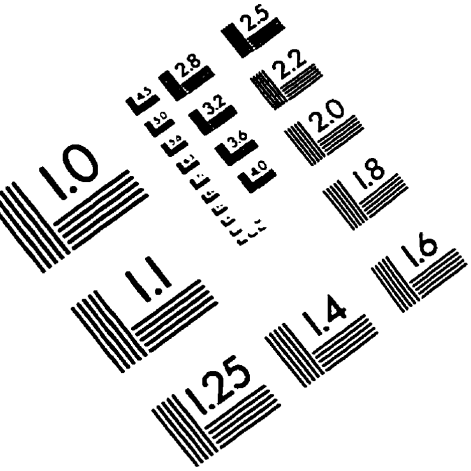
TITLE: Same as above

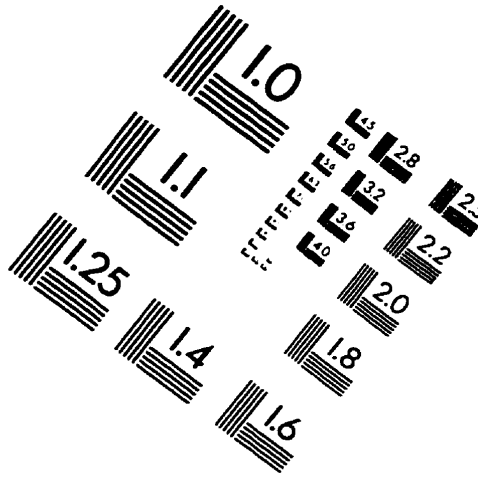
B. B.

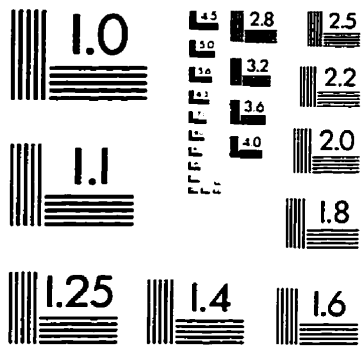
Bessie Borwein. Chairman

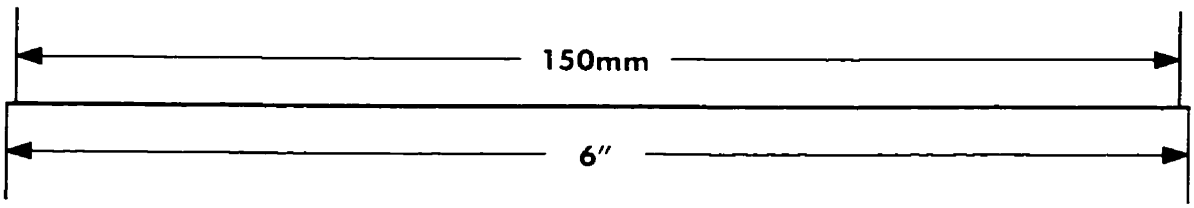
* Hospital Administration

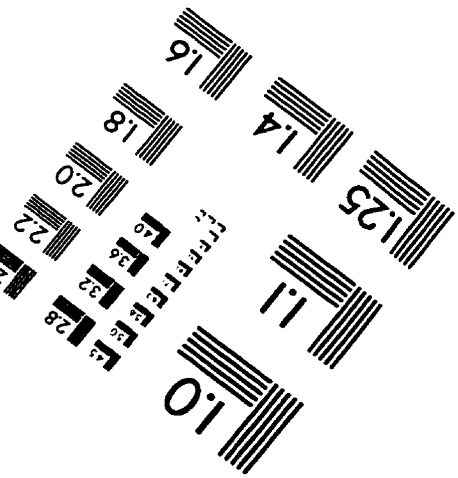
IMAGE EVALUATION
TEST TARGET (QA-3)

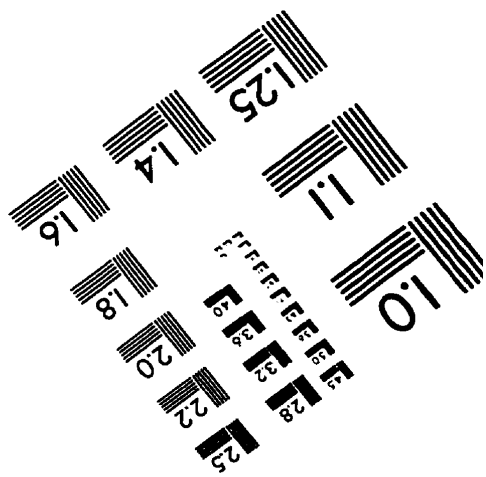












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