Comparison of Tinnitus Masking and Tinnitus Retraining Therapy

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Abstract

Two methods for treating tinnitus are compared. Tinnitus masking has been used for over 25 years, and although this method is used in clinics around the world, there are many misconceptions regarding the proper protocol for its clinical application. Tinnitus retraining therapy has been used clinically for over 12 years and has received considerable international attention. Although these methods are distinctive in their basic approach to tinnitus management, certain aspects of treatment appear similar. These aspects of treatment have created considerable confusion and controversy, especially regarding the use of “sound therapy” as a basic component of treatment. It is the objective of this article to clarify the major differences that exist between these two forms of treatment.

Key Words: hearing disorders, tinnitus

Abbreviations: 2AFC = two-alternative forced choice; BTE = behind the ear; DPOAE = distortion-product otoacoustic emissions; ITE = in the ear; LDL = loudness discomfort level; MML = minimum masking level; TRT = tinnitus retraining therapy

Sumario

El artículo compara dos métodos para el tratamiento del acúfenos. El enmascaramiento del acúfenos se ha utilizado por más de 25 años, y a pesar de que el método ha sido usado en clínicas por todo el mundo, existen muchos conceptos erróneos en cuanto al protocolo apropiado para su aplicación clínica. La terapia de re-entrenamiento para el acúfenos (TRT = tinnitus retraining therapy) ha sido utilizada clínicamente por más de 12 años y ha recibido considerable atención internacional. Aunque estos métodos son diferentes en su enfoque básico sobre cómo manejar el acúfenos, ciertos aspectos terapéuticos parecen similares. Estos aspectos de tratamiento han creado considerable confusión y controversia, especialmente en relación con el uso de “terapia de sonido” como un componente básico del tratamiento. Es el objetivo de este artículo aclarar sobre cuáles son las diferencias mayores que existen entre estas dos formas de tratamiento.

Palabras Clave: trastornos auditivos, acúfenos (tinnitus)

Abreviaturas: 2AFC = escogencia forzada de dos alternativas; BTE = retroauricular; DPOAE = emisiones otoacústicas por productos de distorsión; ITE = intraauricular; LDL = nivel molesto de sonoridad; MML = nivel mínimo de enmascaramiento; TRT = terapia de re-entrenamiento para el acúfenos

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As reported in the companion article (Henry et al., 2002), tinnitus is experienced by 40 to 50 million individuals in the United States, and the tinnitus is so problematic as to be debilitating for about 2.5 million of these persons (Davis and Refaie, 2000). Debatable tinnitus can impact a person emotionally and affect concentration and sleep. Depending on the severity of these effects, tinnitus can further affect job performance, relationships, and social functioning. Because of our increasingly noisy society, the prevalence of tinnitus is expected to increase (Vernon, 1998). Physicians, audiologists, and counselors are thus faced with a rising number of patients with tinnitus as their primary complaint.

For individuals with clinically significant tinnitus, a handful of treatment methods have gained wide acceptance and are generally regarded as viable treatment options. Two of these methods, tinnitus retraining therapy (TRT) and tinnitus masking, are similar in that they both employ “sound therapy,” although they have different rationales and use different protocols for this purpose. These two methods are nonsurgical and nonpharmacologic, rendering them usable in a wide range of different individuals.

Prior to describing and contrasting the two protocols—which is the main objective of this article—a caveat is in order. The founders and primary proponents of TRT and tinnitus masking (P. Jastreboff and J. Vernon, respectively) have each propagated an extensive literature describing their methodology for tinnitus treatment. Other scientists have further written about these methods. For this article, the utmost effort has been made to describe each method in a manner consistent with the extant literature for Drs. Jastreboff and Vernon. Each of these methods is associated with basic principles that have distinguished the methods since their inception. Over the years, however, some of the procedural details have undergone revisions, resulting in some discrepancies between earlier and later writings. This report focuses on the most current viewpoints concerning each method and indicates if such viewpoints have not been addressed in the literature.

The treatment protocol for TRT has been clearly defined, including specific instructions for directive counseling and follow-up appointments. Tinnitus masking has also been formally described in numerous publications as a method of sound-based relief. The published descriptions of “counseling” for tinnitus masking, however, have been limited primarily to the selection and use of ear-level devices to obtain maximum relief from tinnitus. For the actual practice of tinnitus masking in Vernon’s clinic, additional counseling was always conducted. Patient counseling for tinnitus masking in the present report is therefore consistent with what was practiced during that period of time. Also, follow-up contact from patients has always been advised for tinnitus masking, but there has been little mention of appointment schedules following the initial fitting of masking devices.

Purpose

Interest in tinnitus has greatly increased in the last two decades, as evidenced by an abundance of articles and books on the subject. This high level of interest is benefiting tinnitus sufferers by giving them more options for treatment. Unfortunately, these individuals will receive very different advice depending on their source of professional information. The community of tinnitus researchers and clinicians does not operate by a common standard, and the tinnitus patient has almost no means to assess the validity of any claims regarding treatment efficacy.

Tinnitus masking and TRT are two frequently used methods for clinical management of tinnitus. Both of these methods have a long history of development, application, and refinement, as well as a track record of clinical success. To perform treatment with either of these protocols without full knowledge of their rationale and recommended procedures would largely negate the value of years of development. Patients deserve the best treatment available, but all too often well-meaning clinicians do not have sufficient training to provide the highest possible level of service. The delivery of less-than-optimal services argues for the need to implement training programs for clinicians who are the point of contact for tinnitus patients. The present document is an attempt to at least partially remedy this problem by directly comparing the various components of tinnitus masking and TRT. In the following sections, an overview of each of the techniques is provided (Table 1), followed by descriptions of each technique’s assessment procedures, treatment protocols, and reported treatment outcomes.

Terminology

For sound therapy purposes, wearable ear-level devices are used with both TRT and tinnitus masking. These devices can be noise
Table 1 Overview of Basic Components of Tinnitus Masking and Tinnitus Retraining Therapy (TRT)

<table>
<thead>
<tr>
<th>Conceptual basis</th>
<th>Tinnitus Masking</th>
<th>Tinnitus Retraining Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main objective of treatment</td>
<td>Use of sound to mask or partially mask tinnitus</td>
<td>Neurophysiologic model</td>
</tr>
<tr>
<td>Primary purpose of assessment</td>
<td>Produce sense of relief in masking tinnitus</td>
<td>Facilitate habituation to tinnitus</td>
</tr>
<tr>
<td>Critical assessment procedures</td>
<td>Determine if masking treatment will be effective</td>
<td>Determine patient treatment category (TRT categories 0, 1, 2, 3, or 4)</td>
</tr>
<tr>
<td>Terminology used for ear-level noise-generating devices</td>
<td>Audigram, tinnitus evaluation, trial and error of ear-level devices</td>
<td>TRT initial interview, audiogram, loudness discomfort levels</td>
</tr>
<tr>
<td>Terminology used for ear-level combination devices (hearing aid plus noise generator)</td>
<td>&quot;Tinnitus maskers&quot;</td>
<td>&quot;Sound generators&quot;</td>
</tr>
<tr>
<td>Treatment regimen</td>
<td>Use of ear-level devices (tinnitus maskers, hearing aids, tinnitus instruments), counseling</td>
<td>Use of ear-level devices, (sound generators, hearing aids, combination units), counseling</td>
</tr>
<tr>
<td>Follow-up appointment schedule</td>
<td>Minimal follow-ups to ensure proper operation of devices</td>
<td>Follow-ups over 1–2 years at specific intervals</td>
</tr>
<tr>
<td>Primary outcome measure</td>
<td>Successful use of ear-level devices, Tinnitus Severity Index</td>
<td>TRT Follow-Up Interview</td>
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</table>

Tinnitus masking can use any device that presents sound to the ear, and if such a device provides relief—whether or not it totally eliminates that patient's perception of tinnitus—it is referred to as a "masker" (Vernon, 1988). Thus, even hearing aids and combination devices are each referred to as maskers when their main purpose is to provide relief for the tinnitus patient. Further, for tinnitus masking, the combination devices are referred to as "tinnitus instruments" (Vernon and Meikle, 2000).

With TRT, wearable noise generators used for certain categories of patients are never referred to as "maskers" because their function is not to mask. Rather, they are referred to as "sound generators." It is preferential to call them sound generators rather than noise generators because continued use of the term "noise" can have negative connotations for the patient. Combination devices can either be referred to as such or as combination "units."

Tinnitus Masking

The central premise of tinnitus masking involves the use of wearable ear-level devices that deliver sound to a patient's ear(s). The primary purpose of the sound presentation is to produce a sense of relief from the annoyance caused by the tinnitus sound (Vernon, 1977; Vernon and Schleuning, 1978; Vernon and Meikle, 2000). The relief is accomplished by "covering up" the tinnitus sound or by changing the sound of the tinnitus in some way, usually by reducing its perceived loudness (Vernon, 1988; Vernon and Meikle, 2000). These two objectives are referred to respectively as "complete" and "partial" masking. This sense of relief can technically be accomplished using any form of sound that the patient chooses to provide the greatest degree of relief. Ideally, the sound should be presented to the ear on a continual basis, which can be accomplished only by wearable tinnitus maskers, hearing aids, or combination hearing aids/maskers (the latter termed "tinnitus instruments") (Vernon, 1987a).

It should be emphasized that the notion of attaining immediate relief from tinnitus masking may be deceptive because it might suggest that long-term relief should not be expected. Many patients have reported long-term relief from their tinnitus with this method (Vernon and Meikle, 2000). It should be further noted that although a specific counseling protocol has not been described for tinnitus masking, most clinicians do, however, employ a variety of counseling techniques as an adjunct to tinnitus masking. Patient education would be considered part of the tinnitus masking approach because patients are generally counseled about the nature of their hearing loss and their tinnitus, the use of sound to provide tinnitus relief, and activities that may help reduce their perception of tinnitus.
The use of externally generated sound to achieve tinnitus relief was first described in the early part of the nineteenth century by Jean-Marc Gaspard Itard (1775–1838), a French physician and author of the watershed work Traité des Maladies de l'Oreille et de l'Audition (Paris, 1821). The modern era of tinnitus masking commenced in 1976 when Dr. Jack Vernon of the Oregon Health & Science University (OHSU) in Portland described his approach (Vernon, 1976a). The technique was used in a fairly standardized manner at OHSU until Dr. Vernon's retirement in 1996. Tinnitus masking has also been performed at a number of other clinics in the United States and throughout the world, although the specific protocol has not always been consistent among clinics (Vernon, 1987a; Vernon and Meikle, 2000).

During Dr. Vernon's tenure, after audiologic and other types of evaluation had been completed, approximately 60 percent of the patients who were seen at his clinic were considered to be candidates for tinnitus masking and were given a recommendation to obtain some type of wearable ear-level device (Vernon and Meikle, 2000). The various types of devices employed included tinnitus maskers, hearing aids, and tinnitus instruments. Hearing aids are thought to provide tinnitus masking when the patient reports that trial use of the hearing aids in a variety of acoustic environments results in "partial" or "complete" relief by, respectively, reduction or total elimination of the tinnitus sound (probably owing to masking by ambient or background noise) (Vernon, 1976a; Vernon and Schleuning, 1978; Vernon and Meikle, 2000). Tinnitus instruments have been considered particularly useful because they provide the capability of using amplified environmental sound in conjunction with masking noise.

Additional masking help is recommended for many patients through the use of nonwearable devices such as bedside maskers and specially recorded masking tapes and compact discs (Johnson, 1998; Vernon and Meikle, 2000). Use of the prescription drug Xanax (alprazolam) has also been advocated for patients who do not receive relief from tinnitus masking or in cases of severe psychological distress (Johnson et al, 1991). This option, however, is available only in combined efforts with supportive physicians.

A number of studies have reported clinical outcomes data for treatment of large numbers of tinnitus patients using the basic method of tinnitus masking. The resulting data, reviewed by Vernon and Meikle (2000), indicate success rates ranging from 45 to 77 percent. These percentages should be considered equivocal as the methodology and criteria for success were very different between studies.

**Misconceptions of Tinnitus Masking**

Tinnitus masking has been widely misunderstood by therapists (Vernon, 1987a, 1988). Consequently, attempts to provide masking have often resulted in unsatisfactory outcomes, as attested to by the high return rate of maskers to the manufacturers (M. Eldridge, General Hearing Instruments, and E. Parker, Starkey Instruments, personal communication, 2001). It is perhaps unfortunate that the word "masking" was used as a name for this technique because the classic audiologic definition of masking implies something different from what is intended as the purpose of treatment.

Masking is a term that has been used in audiology for many years and can be defined as the "increase in the threshold or threshold shift for one sound in the presence of another" (Gelfand, 1990, p. 307). Gelfand expanded this definition to include "the reduction in loudness that can occur when a second sound is presented, a process referred to as partial masking." Thus, one sound can be completely or partially masked by another sound. Many audiologists do not make a distinction between partial and complete masking. Because of the type of clinical training that most audiologists receive, their interpretation of masking is often the elimination of the perception of one sound by the presentation of another sound. Thus, when the term masking is used to describe a method to treat tinnitus, the assumption may be that a masking sound will be presented in the attempt to eliminate the perception of an individual's tinnitus.

As a further complication, the wearable ear-level devices used for tinnitus masking are referred to as "maskers." Thus, the uninformed audiologist may order such a device for the sole purpose of attempting to totally eliminate the patient's perception of his/her tinnitus. Most audiology programs do not provide formal training for clinical management of tinnitus, yet most audiologists are familiar with the term masking and are aware that maskers are available from hearing aid companies to treat tinnitus. Audiologists are accustomed to fitting hearing aids to treat hearing loss and are at least aware that a masker is a similar device that is used to treat tinnitus. In some cases, the audiologist will insert the device into a patient's ear and tell the
patient to “turn up the noise until it covers the tinnitus.” The device is then deemed successful only if it eliminates the tinnitus sound with the noise from the masker. This approach to tinnitus masking is completely erroneous, yet it continues to be misunderstood and misapplied in the clinical setting. The informed and experienced clinician will advise the patient that complete masking of the tinnitus may not be possible; however, a significant degree of relief may be possible through partial masking of the tinnitus. The use of tinnitus instruments also requires special instruction and without careful counseling will be more prone to failure.

**Differences between Tinnitus Masking and Conventional Masking**

It is important to understand how conventional masking concepts relate to tinnitus. Conventional sound-on-sound masking obeys a number of rules that are consistent between individuals. Such effects have received extensive investigation, and the rules are well defined. Many studies have been conducted to determine if these same rules apply to the masking of tinnitus. These studies have generally concluded that there are many dissimilarities between masking a tinnitus signal and conventional sound-on-sound masking (Feldmann, 1971; Vernon et al, 1980b; Hazell, 1981; Shailer et al, 1981; Mitchell, 1983; Tyler and Conrad-Armes, 1984; Penner, 1987; Penner and Klafter, 1992; Mitchell et al, 1993). For example, with conventional masking, the “critical band” refers to a particular frequency region surrounding a tone. Masking of the tone will occur only if the masking sound contains energy within the critical band. Sounds outside the critical band will not mask the tone. With tinnitus, however, the critical band phenomenon does not apply to most patients. In fact, patients vary widely with respect to their tinnitus “maskability.” For some almost any sound will mask their tinnitus, whereas for others almost no sound will produce masking. Some patients do apparently experience optimal masking when the masking sound approximates the sound of their tinnitus.

In general, the masking of tinnitus does not seem to follow any rules that would apply to all individuals who experience tinnitus. There is a caveat to consider, however, with respect to the studies that have attempted to define the “rules” that would apply to the masking of tinnitus. These studies have relied on identification of the individual’s tinnitus sound using various techniques that have not been documented for obtaining reliable responses. For a valid analysis of tinnitus masking effects, it would be critical to accurately define the tinnitus sound—especially its frequency content. Frequency content is usually defined by performing some form of pitch matching, and most studies that have done repeated pitch matching have shown unreliable results (Penner, 1983; Smith et al, 1991; Tyler, 1991; Henry and Meikle, 2000). Consequently, when a person’s tinnitus pitch is identified, these studies suggest that the pitch match is likely to be inaccurate. If the pitch matches used in the tinnitus masking studies were inaccurate, any findings based on the pitch match data would then be erroneous. This argues for the need to develop a procedure that can reliably and accurately produce an external sound that closely approximates the acoustic parameters of a patient’s tinnitus sensation. When such a procedure is developed and documented, these tinnitus masking studies should be replicated.

**Tinnitus Retraining Therapy**

TRT was developed in the late 1980s by Dr. Pawel Jastreboff at the University of Maryland (he subsequently relocated to Emory University, Atlanta). TRT is a program of tinnitus rehabilitation that is based on the “neurophysiological model” of tinnitus (Jastreboff, 1990). The essence of the model is that tinnitus becomes problematic when nervous systems other than the auditory nervous system become activated in response to the tinnitus signal. These other systems include the limbic system, which is the neural substrate of emotions, and the autonomic nervous system, which mediates a multitude of physiologic functions, including the stress response. For approximately 75 to 80 percent of individuals who experience chronic tinnitus, these nonauditory systems are apparently not involved to a significant degree as a result of experiencing tinnitus (Jastreboff and Hazell, 1998). These individuals are thought to habituate naturally to their tinnitus, that is, they become unaware of their tinnitus in the same way one would typically become unaware of the constant sound emitted by an electric fan. A background sound, such as that produced by a fan, would thus activate the cochlea and the peripheral auditory system, but the neural signal associated with the fan noise does not persist at the cortical level of awareness unless there is reason to listen to the fan. The fan sound has no negative connotations; thus, even the conscious awareness of such
innocuous sound would not cause an emotional or stressful reaction.

For the remaining 20 to 25 percent of individuals who experience chronic tinnitus, the tinnitus signal tends not to be naturally habituated, and the limbic and autonomic nervous systems become involved in reaction to the person's heightened sense of awareness of the signal. The heightened perception and negative reactions comprise a positive feedback loop (a “vicious circle”) that can result in a clinically significant tinnitus condition (Jastreboff et al., 1996; Jastreboff and Hazell, 1998). The TRT protocol was designed to facilitate long-term habituation to the conscious perception of the tinnitus signal through “sound therapy” and to the negative reactions through “directive counseling” (Jastreboff, 1996a; Jastreboff et al., 1996; Jastreboff and Hazell, 1998).

For TRT, the use of sound, not sound devices per se, is the key to achieving habituation to the perception of tinnitus (Jastreboff, 2000; Jastreboff and Jastreboff, 2000). However, the majority of patients treated with TRT are advised to wear ear-level sound generators to optimize the habituation process. Use of the wearable devices for TRT differs from their use for tinnitus masking; the specific objective is not to bring immediate relief by partially or completely masking the tinnitus but rather to provide an additional, monotonous, low-level sound as a background to reduce the “detectability”—a subcortical event—of the tinnitus signal (Jastreboff and Hazell, 1993). Reduced detection of the tinnitus signal at the subcortical level would result in reduced perception of tinnitus at the cortical level.

TRT patients are advised to wear hearing aids or combination units rather than wearable sound generators if their hearing loss presents a significant problem. With TRT, the primary objective of hearing aids is the same as for the sound generators: to interfere with the process of tinnitus detection, and ultimately tinnitus perception, by enriching the patient’s sound environment. The secondary objective of hearing aids is to improve communication ability.

The TRT protocol requires adherence to the recommended regimen for 12 to 24 months, although patients can make significant progress prior to the end of treatment (Jastreboff et al., 1996; Jastreboff and Hazell, 1998). Even when habituation has been achieved, patients are advised to wear the sound generators for another 6 months to ensure that the changes that have occurred in the brain are firmly established (Jastreboff et al., 1996).

Clinical results have been reported from several groups that have performed TRT or treatment consistent with TRT (reviewed below). Based on these reports, 70 to 85 percent of the patients achieved significant benefit from treatment. The results were compiled from analyses of clinical outcomes data that were collected in a prospective manner. That is, outcomes evaluation forms were completed before, during (in many cases), and after treatment. It should be noted, however, that these studies cannot be considered scientifically rigorous; evaluation of treatment outcomes was not designed a priori, no control groups were used, and the criteria for “success” were inconsistent among the groups.

**EVALUATION FOR TREATMENT**

**Audiologic Examination**

Table 2 provides a comparative summary of the different procedures used for evaluating patients for treatment with tinnitus masking or with TRT. The evaluation protocols described below are based on TRT as published by Jastreboff (Jastreboff, 2000; Jastreboff and Jastreboff, 2000, 2001) and tinnitus masking as published by Vernon (Vernon, 1987b; Vernon and Meikle, 1988, 2000). A standard audiolologic evaluation is recommended for both methods (Vernon et al., 1990; Jastreboff and Jastreboff, 2000). With tinnitus masking, the examination is comparable to testing for a routine hearing evaluation, and test results assist in selecting the appropriate masking device (Johnson, 1998; Vernon and Meikle, 2000). For TRT, the audiolologic evaluation is used to assess and separate the issues of hearing loss, tinnitus, hyperacusis, and phonophobia (Jastreboff and Jastreboff, 2000). Test results are also used to develop individualized counseling and to make treatment decisions. The audiogram and pure-tone loudness discomfort levels (LDLs) provide the essential audiometric information for diagnosis and placement into the five TRT treatment categories (defined below). The essential information for assessing TRT treatment outcome is obtained from patients’ responses to the TRT follow-up interview and comparing the responses to those that were obtained using the TRT initial interview prior to treatment (Jastreboff and Jastreboff, 1999a; Henry et al., 2002). An exception is with category 3 patients (i.e., hyperacusis as the primary problem), for whom LDL measurements assist in monitoring and assessing the efficacy of hyperacusis treatment.
### Table 2 Comparison of Evaluation Procedures Used for Tinnitus Masking and Tinnitus Retraining Therapy (TRT)

<table>
<thead>
<tr>
<th></th>
<th>Tinnitus Masking</th>
<th>Tinnitus Retraining Therapy</th>
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<tbody>
<tr>
<td><strong>Primary objective of patient</strong></td>
<td>To select appropriate masking device</td>
<td>To identify patient category (TRT categories 0, 1, 2, 3, or 4)</td>
</tr>
<tr>
<td><strong>assessment</strong></td>
<td>Psychoacoustic evaluation of tinnitus</td>
<td>TRT initial interview</td>
</tr>
<tr>
<td><strong>Primary assessment tool</strong></td>
<td>Hearing thresholds to 8 kHz</td>
<td>Hearing thresholds to 12 kHz</td>
</tr>
<tr>
<td><strong>Audiogram</strong></td>
<td>Very specific procedures; results affect treatment choices and are predictive of outcomes</td>
<td>Nonspecific procedures; results unrelated to treatment methodology or outcome but used for counseling</td>
</tr>
<tr>
<td><strong>Psychoacoustic evaluation of tinnitus</strong></td>
<td>Aids in selecting masking devices</td>
<td>To identify &quot;most troublesome tinnitus&quot;</td>
</tr>
<tr>
<td><strong>Tinnitus loudness and pitch matching</strong></td>
<td>Results predictive of masking effectiveness</td>
<td>Not diagnostic or predictive, but changes shown to correlate with treatment</td>
</tr>
<tr>
<td><strong>Minimum masking level</strong></td>
<td>Specific procedure used; results used for counseling and for treatment enhancement</td>
<td>LDLs at audiometric frequencies important for identifying TRT patient category and for monitoring outcome of treatment for hyperacusis (category 3) patients</td>
</tr>
<tr>
<td><strong>Residual inhibition</strong></td>
<td>LDLs for speech only; results not used to identify hyperacusis patients</td>
<td>Results used for counseling purposes only</td>
</tr>
<tr>
<td><strong>Loudness discomfort levels (LDLs)</strong></td>
<td>Selection of ear-level devices</td>
<td>Device selection based on TRT patient category</td>
</tr>
<tr>
<td><strong>Distortion-product otoacoustic emissions</strong></td>
<td>Trial-and-error procedure in clinic to select most effective devices</td>
<td>TRT initial interview used by all TRT practitioners; primary means of patient assessment</td>
</tr>
<tr>
<td><strong>Selection of ear-level devices</strong></td>
<td>Extensive set of questionnaires used in Dr. Vernon's clinic; other tinnitus masking practitioners use choice of questionnaires</td>
<td></td>
</tr>
<tr>
<td><strong>Questionnaire</strong></td>
<td>Not recommended</td>
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</tbody>
</table>

### Psychoacoustic Assessment of Tinnitus

Psychoacoustic assessment of tinnitus characteristics is recommended for both methods. The rationale and specific procedures for tinnitus testing, however, differ between the two methods. In general, considerable importance is placed on psychoacoustic characterization of tinnitus with tinnitus masking, whereas, for TRT, such testing is considered relatively unimportant.

With tinnitus masking, testing provides information that facilitates identification of effective masking devices (Vernon, 1982, 1988). The evaluation protocol for tinnitus masking consists of four main elements: (1) tinnitus pitch matching, (2) tinnitus loudness matching, (3) minimum masking level (MML), and (4) residual inhibition (Evered and Lawrenson, 1981; Vernon and Meikle, 1988). Specific procedures for these tests had evolved through clinical efforts prior to 1975 (for a review see McFadden, 1982). Further development took place at the Oregon Hearing Research Center, and the protocol was adopted and advocated by the CIBA Symposium on Tinnitus in 1981 in an effort to promote a standardized protocol for clinical tinnitus assessment.

Psychoacoustic characterization of tinnitus for TRT includes pitch matching of the “most troublesome” tinnitus, tinnitus loudness matching, and measurement of MMLs (Jastreboff and Jastreboff, 2000). The pitch and loudness matching data are not used diagnostically or to predict treatment outcome but are considered useful for counseling purposes (Jastreboff, 2000; Jastreboff and Jastreboff, 2000). The measurement of MML is also not considered diagnostic for TRT, but data have been reported showing that MMLs decrease for patients who show improvement and increase for those who do not (Jastreboff et al, 1994; Jastreboff, 1996b).

### Tinnitus Loudness and Pitch Matching

Vernon and Meikle (2000) have listed reasons why documentation of tinnitus loudness and pitch is important for tinnitus masking: (a) to provide baseline information to quantify the perceptual dimensions of tinnitus, (b) to facilitate decisions regarding effective tinnitus masking, and (c) to evaluate treatment effects. Determining a precise pitch match is also considered important because about one-third of the patients are thought to be masked most...
effectively when the masking noise includes the frequency range corresponding to the pitch of their tinnitus (Vernon and Meikle, 1981, 2000).

Pitch matching and loudness matching for tinnitus masking are performed as a combined procedure (Vernon, 1987b; Vernon and Meikle, 1988; Meikle, 1991; Johnson, 1998; Henry et al, 2002). Because inexperienced patients can confuse loudness and pitch (Vernon and Fenwick, 1984), a basic premise for this combined procedure is that pitch matching should be done only with tones that have already been matched in loudness to the patient's tinnitus (Fowler, 1940; Vernon and Meikle, 1981). Loudness matches are obtained to the nearest decibel, and tones are raised in level gradually to avoid inducing residual inhibition, which could alter the perceived tinnitus loudness (Vernon, 1982). Pitch matching is done by presenting loudness-matched tones in alternation using the two-alternative forced choice (2AFC) paradigm (Vernon and Meikle, 1988). The order of test frequencies is also important; testing starts at 1000 Hz and gradually approaches the frequency region that contains the tinnitus pitch for the majority of patients (above 4000 Hz). Test frequencies used are increments of 1000 Hz, and once the tinnitus pitch is bracketed to within a 1000 Hz frequency range, further frequency resolution is possible to provide a precise pitch match (Vernon and Fenwick, 1984). Even with a final pitch match, patients may make the error of "octave confusion." To minimize such error, the 2AFC protocol is used to present the final pitch-matched tone with tones that are one octave higher or lower than the final pitch match (Vernon et al, 1980a; Evered and Lawrenson, 1981).

Tinnitus pitch and loudness matching are also recommended as a component of the patient evaluation protocol for TRT (Jastreboff and Hazell, 1998). With TRT, however, the results are considered to be descriptive only and have no influence on the methodology or outcome of treatment (Jastreboff et al, 1994; Jastreboff, 1996b, 1998). The pitch and loudness match data are used, rather, in the directive counseling component of TRT (Jastreboff, 1998; Jastreboff and Jastreboff, 2000). When tinnitus patients arrive in the clinic, they often have fears and anxieties about the implications of their tinnitus owing to lack of knowledge about the condition. An important aspect of TRT counseling is therefore to "demystify" patients' negative concepts that are associated with their tinnitus (Jastreboff, 2000). This is accomplished through a specified educational protocol, part of which includes an explanation to patients about their tinnitus loudness and pitch matches (Jastreboff, 1998; Jastreboff and Jastreboff, 2000). The tinnitus matching data provide quantification of patients' subjective perception of tinnitus. Also, the tinnitus loudness match at the perceived tinnitus pitch is usually only a few decibels above patients' hearing thresholds (Fowler, 1942; Vernon, 1976b; Henry et al, 1999). Displaying the tinnitus loudness match on patients' audiograms conveys the message that even though the tinnitus may seem loud, the tinnitus signal itself is very faint. As such, it should be a less worrisome concern.

**Minimum Masking Levels**

For both the TRT and tinnitus masking protocols, the measurement of MMLs is recommended. The MML is the level of broadband sound that is required to make tinnitus inaudible. For tinnitus masking, research data have indicated that the decibel difference between the MML and the tinnitus loudness match may be predictive of the effectiveness of masking to relieve the distress owing to tinnitus (Vernon et al, 1990; Vernon and Meikle, 2000). If the MML is less than or equal to the loudness match, acceptability of tinnitus masking is considered likely. If the MML is greater than the loudness match, success with tinnitus masking is less likely. Thus, for tinnitus masking, MML measurements are an important component for assessing the potential efficacy of treatment. For TRT, however, the MML does not have any predictive or diagnostic value but has been shown to correlate with the effects of treatment (Jastreboff et al, 1994). That is, for patients showing improvement during treatment with TRT, a corresponding decrease in the MML has been observed.

**Residual Inhibition**

The fourth element of tinnitus evaluation for tinnitus masking is to assess for the phenomenon of residual inhibition. Residual inhibition is the effect of temporary suppression or elimination of tinnitus that is often observed following auditory stimulation (Vernon and Meikle, 1988). To clinically test for residual inhibition, broadband noise (3–12 kHz) is presented binaurally to patients at 10 dB above their binaural MML. The noise is delivered for 60 seconds and then terminated, at which time patients are asked to describe any perceived changes to their tinnitus.
If the tinnitus is reduced or abolished, they are asked to comment regarding changes to the tinnitus percept during recovery of the tinnitus to its normal level. These comments and the duration of the effect to full recovery are recorded.

Residual inhibition occurs for about 90 percent of tinnitus patients and demonstrates (often dramatically) to patients that their tinnitus is capable of modification, thus giving them encouragement for tinnitus relief (Henry and Meikle, 2000; Vernon and Meikle, 2000). It has also been observed that a patient receiving tinnitus masking can induce residual inhibition through the use of maskers (Vernon, 1982). Patients are therefore instructed to be cognizant of this effect and to reduce their use of maskers accordingly if it occurs. Hearing aids can be used to produce masking, but they apparently do not induce residual inhibition (Vernon, 1988).

Although testing for residual inhibition is commonly performed to evaluate for treatment with tinnitus masking, this test is not recommended for TRT. Inducing residual inhibition to patients in a TRT program would mislead them as to the goals of TRT (P Jastreboff, personal communication, 2001). Attempts to induce temporary suppression of tinnitus would contradict the TRT protocol that is designed to facilitate habituation to tinnitus.

Other Clinical Tests

**LDLs for TRT**

For TRT, the measurement of LDLs is considered crucial for determining the course of treatment and for monitoring treatment outcome for category 3 patients who are treated primarily for their hyperacusis (Gold et al, 1995; Jastreboff, 1996b; Jastreboff and Jastreboff, 2000). The LDLs are evaluated at audiometric frequencies up to 12 kHz and at the frequency matched to the tinnitus pitch (Jastreboff and Jastreboff, 2000). Each LDL is repeated, and the second measurement is recorded. Measurement of LDLs is important for TRT because of TRT’s emphasis on assessing loudness tolerance. The LDLs define the upper limits of a patient’s dynamic range at conventional audiometric frequencies (Skinner, 1988). This information assists the audiologist in precisely determining the extent of a patient’s loudness tolerance, and the baseline measurements are used as a reference to evaluate the effects of treatment. It has been reported that approximately 40 percent of patients who are assessed for tinnitus will exhibit some degree of loudness intolerance, grossly defined as an average of tonal LDLs being below 100 dB HL (Coles and Baskill, 1996; Jastreboff, 2000; Jastreboff and Jastreboff, 2000). With treatment primarily for loudness intolerance (where tinnitus is usually present but as a secondary problem), the LDLs are often seen to increase in correspondence with the patient’s reported improvement in the ability to tolerate sound (Hazell and Sheldrake, 1992; Vernon and Press, 1998; Gold et al, 1999; McKinney et al, 1999a; Wolk and Seefeld, 1999; Formby and Gold, 2002).

**LDLs for Tinnitus Masking**

For tinnitus masking, tonal LDLs are not part of the audiometric assessment, although LDLs for speech are done as for any standard audiologic examination (Johnson, 1998). These LDLs can also be useful if choosing between a linear or compression tinnitus instrument. Masking patients are generally not treated for loudness sensitivity unless the loudness sensitivity is severe (Vernon and Press, 1998). Such patients typically cannot tolerate any degree of everyday sound, and they rely heavily on the use of earplugs or earmuffs (or both). Such extreme symptoms are not defined by audiometric measurement but rather by patient report.

It is important at this juncture to define hyperacusis from Vernon’s perspective. His definition of hyperacusis is “the collapse of loudness tolerance so that almost all sounds produce loudness discomfort” (Vernon and Press, 1998). This definition would certainly result in a lower rate of hyperacusis than the 40 percent reported by Jastreboff and others (Coles, 1996; Jastreboff, 2000; Jastreboff and Jastreboff, 2000). Vernon has often been cited as reporting a hyperacusis prevalence rate of 0.3 percent. This figure was derived from a survey that was conducted among the membership of the American Tinnitus Association (ATA) (Reich and Griest, 1992). Vernon and Press (1998) referenced this survey as involving “35,000 patients from which 112 (0.3%) hyperacusis patients were revealed” (p. 225). The “35,000 patients” refers to the number of ATA members who received the ATA journal that contained a notice asking them “if they had hyperacusis and would like to participate in the survey” (Reich and Griest, 1992, p. 250). As a result of this notice, only 30 to 40 people completed the survey. A separate group of individuals who were in contact with the ATA also completed the surveys, totaling 112 respondents. Thus, the reported per-
percentage of 0.3 was not a true prevalence rate and should not be cited as such.

**Distortion-Product Otoacoustic Emissions**

Distortion-product otoacoustic emission (DPOAE) testing is recommended for patients evaluated for TRT but not for those evaluated for tinnitus masking. With TRT, the results of DPOAE testing have not been shown to be either diagnostic or predictive of TRT success or to correlate with the effects of treatment. Rather, DPOAE data are used as part of the TRT directive counseling protocol (Jastreboff and Jastreboff, 2000). The directive counseling includes a description of the cochlear hair cells and how damage to the outer hair cells might be the cause of tinnitus generation (Jastreboff, 2000). An explanation of the results obtained with DPOAE testing provides an analysis of what is assumed to be outer hair cell function (Brownell, 1990; Burch-Sims and Ochs, 1992), which furthers the patient’s understanding of tinnitus generation (Gray et al, 1996). A similar approach may be used for patients receiving tinnitus masking; however, it has never been recommended as part of a tinnitus masking protocol.

**PRESCRIBING AND INITIATING TREATMENT**

**Tinnitus Masking**

**Selection of Ear-Level Devices**

The tinnitus evaluation provides information to guide implementation of the tinnitus masking program if the patient decides to pursue treatment (Vernon, 1982, 1988; Johnson, 1998). If the clinician and the patient agree that tinnitus masking has such potential, they will then work together to determine which device or combination of devices will offer the greatest degree of relief from tinnitus distress. Final treatment recommendations require the patient to try a variety of ear-level devices to determine whether a wearable device will provide relief (Vernon and Meikle, 2000). If so, the device is selected at that time.

Wearable ear-level devices (maskers) that can be used for tinnitus masking include behind-the-ear (BTE) and in-the-ear (ITE) configurations, with various models that provide amplification, masking noise, or both. For many patients, tinnitus maskers are recommended. If the patient also needs hearing amplification, tinnitus instruments (combination devices) may be recommended. Wearable devices with selectable frequency ranges are considered important for those patients whose tinnitus can be masked only by frequencies close to the pitch of their tinnitus.

Maskers are selected by the patient through a trial-and-error procedure that is facilitated by the clinician (Vernon and Meikle, 2000). For optimal selection of devices, an array of different maskers (BTE, ITE, different frequency ranges, or, preferably, with selectable frequency range) must be on hand in the clinic for patient trial. For each trial, the patient’s subjective impression and the effectiveness and acceptability of tinnitus masking are noted. For ITE models to be tested, the clinic should have generic devices that are small enough to fit into most ears. When trying such devices, there is, of course, the awareness that they will not be as good as the custom-fitted devices.

Fittings of devices can be unilateral or bilateral, depending mainly on which combination of devices produces the most effective masking (Vernon, 1987a; Vernon and Meikle, 2000). For example, most patients with bilateral tinnitus require bilateral devices, but not all patients, because some bilateral tinnitus can be masked unilaterally. The final device configuration for a patient thus might be one or two tinnitus maskers, one or two hearing aids, one or two tinnitus instruments, or some combination of these such as one hearing aid and one tinnitus instrument. It is ultimately the patient’s satisfaction that determines the final device selection.

Hearing aids are the first option tried whenever a patient has a significant hearing loss (Vernon, 1988). It is important that the trial with hearing aids be done not in a soundproof room but in a normal room with normal ambient noise levels (Vernon and Meikle, 2000). If the patient’s tinnitus is high-pitched, however, hearing aids are likely not to help unless the patient is one of those for whom almost any sound will mask the tinnitus (Vernon, 1987a). In such a case, a hearing aid may provide just enough background sound to provide such masking. During the clinic procedure used for evaluation of potential masker devices, hearing aids are usually tried first to determine if they alone will provide the necessary masking relief. If they do not, then tinnitus instruments are tried, which provide masking noise that is variable in amplitude independent of the amplification provided by the hearing aid (Vernon and Meikle, 2000).
Patients with significant hearing loss typically receive benefit from tinnitus instruments (Vernon and Meikle, 2000). There are a number of tinnitus instruments available that are produced by various companies. As examples, Starkey Corporation (Minneapolis, MN) makes two versions of tinnitus instruments: the TML (masker plus linear hearing aid) and the TMC (masker plus compression hearing aid). General Hearing Instruments (New Orleans, LA) and Siemens (Minneapolis, MN) released new devices in 2001, respectively, the "Harmony" and "Sereniti TCI-C." It is important to mention that some earlier tinnitus instruments did not have two independent volume controls for the masker portion and the hearing aid portion. Instead, they had only one volume control to adjust both masker and hearing aid together. That arrangement is unacceptable and is no longer made by any manufacturer to our knowledge.

During Dr. Vernon's tenure, when a recommendation was made for a masker, the recommendation was for a hearing aid 12 percent of the time, a tinnitus instrument 67 percent of the time, and a tinnitus masker 21 percent of the time (Vernon, 1988). This contrasts with TRT, which uses sound generators for 70 percent of the patients (Jastreboff, 2000).

**Modifications of Treatment**

Questionnaires should be administered to provide information on many aspects of the patient's condition, lifestyle, and general health status that would enter into treatment recommendations (Vernon et al, 1990; Meikle, 1991). Patient's responses to these questions will assist in determining any modifications of treatment. Discussing the patient's individual needs, as was done under Dr. Vernon's direction, includes advice and education to the patients that could be considered "counseling."

For example (M. Meikle, personal communication, 2001), if the patient reports sleep disturbance, treatment might include bedside maskers, a masking pillow, or ITE devices to be worn at night as needed. If the patient reports the use of firearms, a noisy work environment, or other types of noise exposure, then advice is given regarding the importance of avoiding noise to avoid the exacerbation of tinnitus (see also Vernon, 1982). Some patients may be counseled to change their work environments or even their occupations. If the patient reports difficulty hearing speech, difficulty interacting with others, reduction of social life, or reduced enjoyment of life, then counseling is given regarding hearing aids' ability to reduce these problems and to reduce stress and fatigue. There are many other examples of patient counseling that are based on clinician examination of patients' answers indicating such things as dizziness; need for better medications; attention to chronic conditions such as diabetes, hypothyroidism, allergies, cardiovascular disease, etc.; temporomandibular joint disorder; potential need for acoustic neuroma evaluation; revision of previous middle ear surgery; etc. A major aim of such counseling is to place the patient's tinnitus within a medical context and to treat it with the same attention to diagnostic detail that would accompany a thorough examination by an internist confronted with a puzzling physical condition. That diagnostic care is also very reassuring to patients.

**Tinnitus Retraining Therapy**

**Patient Categories**

Treatment decisions for TRT are based primarily on results of the TRT initial interview (Jastreboff and Jastreboff, 1999a; Henry et al, 2002). The initial interview was developed for use in determining the extent of a patient's problem and to assign the patient to one of five treatment categories (categories 0, 1, 2, 3, and 4). Four components are used to determine the category for each patient: (a) how much the tinnitus impacts the patient's life, (b) the patient's subjective perception of the significance of any hearing loss, (c) the degree to which sound tolerance might be a problem, and (d) the effect of prolonged worsening of the patient's condition (either tinnitus or hyperacusis) following exposure to moderate-to-loud levels of sound (Jastreboff and Jastreboff, 2001; Henry et al, 2002). The information obtained from the questionnaire and from the audiometric testing is used to place the patient into one of the five TRT categories, and treatment is conducted accordingly.

Category 0 refers to patients who are minimally bothered by their tinnitus. Following evaluation, they are offered directive counseling, which would include a description of the TRT neurophysiologic model and advice as to the use of environmental sound to optimize tinnitus habituation (Jastreboff et al, 1996; Jastreboff and Jastreboff, 1999b). Category 1 describes patients who have a significant problem with their tinnitus. For these patients, the TRT initial interview will reveal that at least one major life
Ear-Level Devices Used for TRT

With TRT, ear-level devices are required for all categories of patients except category 0 (sound generators are required for categories 1, 3, and 4 and amplification is required for category 2). The devices are always fit bilaterally, regardless of the perceptual location of the patient's tinnitus (Jastreboff and Hazell, 1998; Jastreboff, 2000).

Sound generators used with TRT must meet certain performance criteria, such as frequency content and stability of the wide-band noise, precise adjustment of volume at low levels, and open-ear configurations (Jastreboff, 1994; Jastreboff et al, 1996). At this time, only four models of wearable sound generators have been found by Dr. Jastreboff to be acceptable. These include the Viennatone (Starkey Corp.) Silent Star BTE device, the General Hearing Instruments' Tranquil, and a device built in Spain by Audiphon (Jastreboff and Jastreboff, 2000). The Siemens Sereniti TCI (ITE or BTE) has recently been added to the list of approved sound generators. BTE devices should be coupled to a free-field earmold (e.g., model #19 earmold, Microsonic Inc., Ambridge, PA).

Amplification is used only if the hearing loss is subjectively a significant problem for the patient (Jastreboff and Hazell, 1998). Thus, the decision to use amplification does not depend on the audiometric evaluation but rather on how the hearing loss impacts the patient's life. If amplification is required, these patients are classified as category 2 according to the TRT categorization schema (Jastreboff, 1999a; Jastreboff and Jastreboff, 2000, 2001).

Until this year, combination units were not approved for use with category 2 patients. Recently, however, two combination units have become commercially available that meet the performance criteria as for the sound generators. These combination units include the General Hearing Instruments’ “Harmony” and the Siemens “Sereniti.” Because combination units are just now being used with TRT, there are as yet no clear guidelines as to how to select between either a hearing aid or a combination unit for a given patient. In general, it seems preferable to fit most of these patients with combination units to provide controlled, continuous output of broadband noise in addition to amplified environmental sound. The trade-off to using combination units is that their use precludes the option to select from all models and makes of hearing aids, which might prevent an optimal hearing aid fitting. Some patients, especially patients with less bothersome tinnitus, may do well using hearing aids alone.

“SOUND THERAPY”

Both tinnitus masking and TRT use the presentation of continuous sound to a patient as “sound therapy” to improve the patient's tinnitus condition. For both methods, this is generally accomplished through the use of wearable noise generators and/or hearing aids as well as the addition of some type of sound(s) to the patient's living environment.

The purpose of sound therapy, however, is entirely different between the two techniques (Table 3). For TRT, the purpose of sound therapy (along with directive counseling) is to facilitate long-term habituation to the tinnitus signal (Jastreboff, 1999b). For tinnitus masking, sound therapy is used to bring about immediate relief from the patient's distress that is caused by tinnitus (Vernon, 1977, 1987a, 1988). Patients treated with TRT are told not to expect any improvement for the first few months of treatment, whereas tinnitus masking patients are told that treatment should bring immediate relief. Long-term relief for tinnitus masking would be evidenced by patients who continue to use their maskers for years or who return for their second or third set of maskers (Vernon and Meikle, 2000).
Table 3 Comparison of Sound Therapy Procedures Used for Tinnitus Masking and Tinnitus Retraining Therapy (TRT)

<table>
<thead>
<tr>
<th>Purpose of sound therapy</th>
<th>Tinnitus Masking</th>
<th>Tinnitus Retraining Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>To effect immediate relief from tinnitus distress</td>
<td>“Expect immediate relief”</td>
<td>To facilitate long-term habituation to tinnitus</td>
</tr>
<tr>
<td>Advice to patients</td>
<td>All types of tinnitus maskers, hearing aids, tinnitus instruments</td>
<td>“Don’t expect any improvement for the first few months of treatment”</td>
</tr>
<tr>
<td>Ear-level devices used for sound therapy</td>
<td>Trial and error—patient choice as to which style/model is most effective</td>
<td>Sound generators (limited to approved models), hearing aids (all types—open ear fittings), combination units (also limited)</td>
</tr>
<tr>
<td>Criteria for selection of ear-level devices</td>
<td>Prescribed schedule initially; then wear as desired</td>
<td>Devices selected according to patient category</td>
</tr>
<tr>
<td>Device fittings</td>
<td>Recommended for specific listening/masking periods</td>
<td>Bilateral</td>
</tr>
<tr>
<td>Daily use schedule of devices</td>
<td>Recommended as part of the need to continually provide for low-level background sound</td>
<td>Use during all waking hours</td>
</tr>
<tr>
<td>Use of augmentative sound sources (special compact discs, bedside sound machines, etc.)</td>
<td>Recommended for specific listening/masking periods</td>
<td>Broad band to activate greatest number of auditory nerve fibers</td>
</tr>
<tr>
<td>Ear-level noise devices</td>
<td>Any noise band, any shaping that provides most effective masking</td>
<td>Adjusted to “mixing point” at beginning of day; no readjustments while devices are in ears</td>
</tr>
<tr>
<td>type of noise</td>
<td>Adjusted according to patient preference</td>
<td>Generally 1–2 yr—until habituation is achieved</td>
</tr>
<tr>
<td>Adjustment of noise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term use of devices</td>
<td>No limit; use as long as they are helpful</td>
<td></td>
</tr>
</tbody>
</table>

Use of Augmentative Sound Devices

Patients in all TRT categories are advised to “enrich their sound environment” by avoiding quiet situations (Jastreboff and Hazell, 1993; Jastreboff et al., 1996). Thus, the use of external sound sources, such as bedside sound machines, tabletop fountains, etc., is generally encouraged for TRT (Jastreboff, 1998, 2000).

With tinnitus masking, patients are also encouraged to use augmentative sound but generally for more specific tinnitus-relief requirements. Prior to the commercial availability of tabletop noise generators, patients were advised to use “FM masking” at bedtime to assist in sleeping by detuning an FM radio to produce broadband noise (Vernon, 1977, 1982; Vernon and Schleuning, 1978). There are currently a number of commercial tabletop devices that present a variety of digitally recorded sounds. Tinnitus masking patients are further encouraged to use special compact discs that are designed to provide temporary tinnitus relief (Johnson, 1998; Vernon and Meikle, 2000). A set of six such special compact discs is provided by Petroff Audio Technologies (Northridge, CA). This set, termed Dynamic Tinnitus Mitigation, provides various masking sound formats.

ONGOING TREATMENT

Both TRT and tinnitus masking require patients to wear their ear-level devices for an extended period of time. A patient’s compliance with the prescribed protocol of device use will depend largely on motivational factors, in the same way that hearing aid use depends on the hearing-impaired patient’s perceived hearing handicap (Dempsey, 1994).

Tinnitus Masking

Adjustment of Ear-Level Devices

With tinnitus masking, adjustment of the maskers is ultimately under the patient’s control and is done using any criteria that the patient deems necessary to obtain maximum relief from the tinnitus sound. Patients who are newly fitted with maskers, however, are provided with a masker use schedule that is designed to meet their individual needs (Vernon, 1987a). Once comfortable with the maskers, patients can adopt a “demand schedule” and set the output at any desired level, resulting in either partial or complete masking. Again, the purpose is not necessarily to obscure
the tinnitus sound but to promote relief from the tinnitus.

The frequency content of the noise is also a variable that may be manipulated by the patient, within the limitations of the masking device (Vernon, 1982). If a tinnitus masker is used that has selectable noise bands, each noise band can be varied in level to obtain a noise spectrum that provides maximum relief. Hearing aids also may be adjusted to selectively amplify certain frequency regions for optimal tinnitus relief (Vernon and Meikle, 2000). For example, if a patient has a high-frequency tinnitus sound, the high-frequency output of the hearing aid may be boosted specifically to enhance relief. Multimemory hearing aids can be used for a similar purpose (M. Schechter, personal communication, 2002).

Potential for Residual Inhibition to Provide Relief

An often-cited result of sound therapy using tinnitus masking is that it can induce the phenomenon of residual inhibition (temporary reduction or elimination of tinnitus following stimulation with sound) (Vernon, 1982, 1988; Vernon et al, 1991; Vernon and Meikle, 2000). An aspect of treatment that is important for some patients is, therefore, the production of residual inhibition through the use of their masking devices. Some patients find this to be very effective and will learn to wear their maskers only as much as necessary to put them into a state of residual inhibition. In this way, they do not have to wear their maskers as much as they would otherwise to obtain relief from their tinnitus. With the residual inhibition effect, they can wear their maskers for a period of time and then remove the maskers once residual inhibition has been induced. The maskers are reinserted once the tinnitus returns to its full intensity or when patients perceive the need to wear them again.

Some patients also find that residual inhibition becomes longer lasting over time, that is, after several months of using maskers, they begin to notice longer and longer periods of residual inhibition when they remove their masking device(s) (Vernon, 1982; Vernon and Meikle, 2000). Many patients, however, do not experience long periods of residual inhibition. For these patients, there should be a de-emphasis on expecting residual inhibition to avoid a sense of failure or eventual rejection of the devices.

There are no data available on the prevalence of residual inhibition induced by treatment with tinnitus masking, and it is emphasized by Vernon and Meikle (2000) that residual inhibition is not the primary objective of masking. If it occurs, it is considered a “bonus” of treatment.

Duration of Treatment

Tinnitus masking patients are instructed to wear their devices on a prescribed schedule during the early period of treatment and only as needed for relief when they have acclimated to wearing the maskers (Vernon, 1987a). There is, therefore, no time limit as to how long they will wear their devices. In fact, Vernon and Meikle (2000) considered the long-term use of tinnitus maskers to provide “convincing evidence that these are truly helpful to patients” (p. 341). The authors later pointed out, however, that “one may not conclude that stopping use of masking indicates a masking failure” (p. 344). Thus, for tinnitus masking, the long-term use of a tinnitus masker can be any duration the patient requires to obtain the needed relief. There are apparently no prospective studies (even uncontrolled) that have precisely defined tinnitus masking success with an evaluation of the percentage of patients who achieved such success.

Tinnitus Retraining Therapy

For all patients treated with TRT, an enriched sound environment is considered essential. Use of sound generators, however, is limited to certain patient categories (Jastreboff, 2000). For category 0 patients, TRT is conducted using only directive counseling and enrichment of the patient’s sound environment without the use of wearable devices. Category 2 patients use hearing aids or combination units. For sound therapy, it is the use of sound itself rather than the use of any particular device that is most important. Theoretically, any TRT patient, except those requiring amplification, could achieve tinnitus habituation without the use of wearable devices. The continual necessity of providing an enriched sound environment, however, is not a practical approach for most patients. The wearable sound generators go wherever the patient goes, thus ensuring an enriched sound environment regardless of the ambient noise present at any given moment. Broadband noise delivered directly to the ear causes a steady and increased discharge rate from a large number of nerve fibers in the auditory nervous system. Providing such a constant
noise background in the auditory nervous system may be important for promoting habituation to tinnitus.

Category 2 patients are instructed to wear their hearing aids (or combination units) all of their waking hours and also to enrich their sound environment by making sure that low-level sound is always present (Jastreboff, 1998). These patients are told that the primary purpose of the hearing aids is to increase the level of sound entering their ears and that improvement in communication is of secondary benefit (Jastreboff et al, 1996; Jastreboff and Hazell, 1998). Optimal fitting of hearing aids, however, is important for achieving optimal results with TRT (Hazell, 1999). The clinician must weigh the potential benefits of any particular hearing aid against the benefit from a combination unit. There are limited combination units on the market and even fewer that are recommended for TRT. If the delivery of broadband noise directly to the ear is indeed important for promoting habituation, combination units would normally be the first choice.

**Adjustment of Devices for Sound Therapy**

When patients use wearable sound generators in conjunction with their TRT program, the only sound available for presentation to the patient is broadband noise delivered by the approved sound generators (Jastreboff, 1994; Jastreboff et al, 1996). The noise can be varied in output but only according to a specific protocol. In category 1 (the most common category), patients are told to raise the level of the noise until it just mixes or “blends” with the tinnitus (i.e., the tinnitus and the broadband noise are equally audible to the patient) (Jastreboff, 1998). The noise is then lowered to just below the mixing level. Patients are also told to establish this level when they first put on the sound generators and then to make no further adjustments that day as long as the sound generators are in their ears. The philosophy with TRT is to “set and forget.” If a patient were allowed to make adjustments of the noise level throughout the day, he/she would be constantly monitoring the noise in relation to the tinnitus. Such constant attention paid to the tinnitus and to the noise would be counterproductive to the main purpose of TRT, which is to facilitate tinnitus habituation.

With TRT, various methods of enriching a patient’s sound environment are used, depending on the patient’s category (Jastreboff, 1998). This basic premise emphasizes the point made above that the results obtained from tinnitus loudness and pitch matching have no influence on the type of sound therapy used with TRT because tinnitus loudness and pitch matching do not influence category assignment. If a person wears hearing aids as part of his or her TRT program, the frequency response of the hearing aids is not made relative to the tinnitus. The use of hearing aids in category 2 is to provide access to the auditory system for the environmental sounds that the hearing loss frequencies inhibit. There is no real need to provide significant amplification in those frequencies at which there is no loss. The hearing aids are set as one would set them for a non-tinnitus patient, with the exception that open-ear fittings are important to avoid occlusion of the ear (which would enhance tinnitus in quiet) and to allow normal entry of environmental sounds into the ear (Jastreboff and Hazell, 1998). The protocol for use of the hearing aids includes instructions for patients to use the hearing aids during all waking hours for continuous sound enrichment.

**Duration of Treatment**

Patients treated with TRT are instructed to wear their sound generators for at least 8 hours per day (Jastreboff, 1998) or their hearing aids (or combination units) for all of their waking hours (Jastreboff and Hazell, 1998). It should be noted, however, that the intent is for patients to wear either their sound generators or their hearing aids “as much as possible throughout the day,” as taught in the TRT instructional courses (Jastreboff and Jastreboff, 1999c).

TRT patients are told that they will wear their sound generators for approximately 18 months and that at the end of treatment, they will not need to wear the devices any further (Jastreboff and Hazell, 1993, 1998; Jastreboff et al, 1996). Some patients do, however, continue use of their sound generators, and they are told that if their tinnitus “resurfaces,” they should use the devices for short periods of time to restore their previous level of habituation (Jastreboff and Hazell, 1993).

**COUNSELING**

If counseling is conducted in a comprehensive manner, there are probably many overlapping issues that are discussed with patients in both forms of therapy. For both methods, successful use of wearable devices for sound therapy cannot be expected without adequate counseling.
Counseling and TRT

Sound therapy and "directive counseling" are the two critical components of treatment with TRT (Jastreboff, 1998). The directive counseling protocol is designed to educate the patient so as to "demystify" the tinnitus, that is, to remove the negative thoughts that are associated with the tinnitus (Jastreboff, 2000). These negative associations must be removed for habituation to occur (Jastreboff and Hazell, 1998). If a patient continues to have negative thoughts about his/her tinnitus, habituation will be prevented (Jastreboff et al, 1996). For some patients (category 0, estimated at 20% of cases) directive counseling alone can be effective for facilitating the process of habituation (Jastreboff, 2000).

Although sound therapy is considered essential for TRT, the use of sound generators (or hearing aids) is, in theory, not essential (Jastreboff, 2000). Jastreboff (1995) stated that "Proper counseling, including a clear explanation of the physiology of hearing and present knowledge about tinnitus generation and perception, is the first and essential part of any treatment" (p. 85). For TRT, a specific protocol of directive counseling has been repeatedly published, and TRT can be conducted using only directive counseling and enrichment of the patient’s sound environment (Jastreboff, 2000).

Counseling and Tinnitus Masking

For tinnitus masking, no specific educational or counseling protocol has been published (in contrast to the use of a standardized counseling protocol that has been spelled out in detail for TRT). That, of course, does not mean that counseling is not used in conjunction with tinnitus masking or that counseling is not important. In Dr. Vernon’s clinic, counseling was an integral component of the evaluation and treatment process, and Vernon continues to provide telephone counseling 1 day per week. His approach to tinnitus patients has always been one of careful listening and the dispensation of advice specific to their particular circumstances. He has recently written a book (coauthored by B. Tabachnick Sanders) that provides his responses to a wide range of questions from tinnitus sufferers (Vernon and Sanders, 2001). This book could be considered a composite of the range of advice that was dispensed in his clinic, and such advice must certainly be considered “counseling.” In the book, Vernon presents his view on counseling: “Counseling, in and of itself, is not always a satisfactory solution for people with tinnitus. But when it is paired with masker or sound generator therapy or with needed medication (like an antidepressant), the two therapies together can be greater than the sum of their individual parts. Sometimes the counseling component makes other therapies successful” (p. 56). He responded to another patient: “We encourage you to take advantage of any counseling opportunity. If you can find a therapist who is willing to explore the intricacies of tinnitus and with whom you feel a rapport, you will be on the road to manageable tinnitus” (p. 57).

Vernon’s numerous articles clearly place their focus on the use of sound, both to evaluate and to treat the tinnitus patient. In some of his articles, however, Vernon does make specific counseling recommendations. He points out the necessity for patients to fully understand the purpose and limitations of tinnitus masking (Vernon, 1987a). Tinnitus masking practitioners are advised to counsel their patients to avoid potentially exacerbating factors such as stress, fatigue, noise exposure, caffeine, aspirin, and alcohol (Vernon, 1982, 1987b). Vernon and Meikle (2000) discussed the preponderance of sleep problems in tinnitus patients and various strategies to help patients achieve normal sleep. If the patient is a candidate for tinnitus masking, further explanation and counseling are done to explain how masking works (e.g., relating masking to patients’ experiences with the noise of a shower or kitchen faucet) (Vernon and Meikle, 2000), the importance of using maskers at the lowest sound level needed to provide relief (Vernon and Fenwick, 1984; Vernon and Meikle, 2000), that masking should be used only when it is found to be beneficial (Vernon, 1987b), and that tinnitus maskers can be used all day long (and some all night), but that such extended use is not necessary (Vernon, 1987a).

Many of Vernon’s articles include descriptions of techniques to conduct audiologic and tinnitus testing, procedures to determine a patient’s acceptability of masking, and the trial-and-error approach to identifying appropriate ear-level devices (Vernon, 1987b, 1988; Vernon and Meikle, 1988, 2000; Vernon et al, 1991). Such testing and evaluation would inherently include explanations to the patient that would be educational with regard to the audiogram, hearing loss, tonal versus noise stimuli, high-pitched versus low-pitched tones, and the relevant acoustic parameters of tinnitus.

At Vernon’s clinic, there was a consistent effort to procure patient data in the form of
questionnaires, including medical, hearing, noise exposure, and tinnitus histories (Meikle and Walsh, 1984; Meikle et al, 1984, 1995; Johnson, 1998). Patient responses to the various questions were useful in guiding the practitioner in a discussion of various concepts relating to the patient's situation, including hearing difficulties, medications, health problems, and possible causes of the tinnitus such as noise exposure, head trauma, ototoxicity, and pharmaceutical agents. Patients therefore received educational information specific to their personal circumstances, and this advice was generally intended to allay negative thinking and fears related to their tinnitus.

**FOLLOW-UP VISITS**

**Tinnitus Retraining Therapy**

For TRT, follow-up visits are considered essential for the success of treatment, and patients are advised to return to the clinic (or be in touch by telephone if distance precludes repeat in-person visits), at a minimum, after 3 and 6 weeks and at 3, 6, 12, and 18 months (Jastreboff, 1998). Counseling is repeated at each of these visits to reinforce the fundamental principles of TRT. Also, the TRT follow-up interview (Jastreboff and Jastreboff, 1999a) is conducted by the clinician during each of these follow-up visits. The audiogram and LDL measurements are repeated at each 6-month interval (Jastreboff, 1998).

**Tinnitus Masking**

For tinnitus masking, clinicians who dispense maskers are advised to provide follow-up service and to survey their patients regarding masker use at 6 months and 1-year postfitting (Vernon, 1987a). Such contacts are primarily to obtain follow-up information concerning treatment efficacy and to provide useful feedback to the clinic. In an earlier report, Vernon and Schleuning (1978) stated that patients are encouraged to make "weekly contact" with the clinic for the purposes of obtaining advice and reporting progress. In a later report, Vernon recommended that all patients who are fitted with a device return to the clinic in 1 month (Vernon, 1987b). Thus, with tinnitus masking, it is not clear whether return visits at fixed intervals are required, and it appears that follow-up counseling is limited primarily to ensuring that patients are using their devices correctly.

**REPORTS OF CLINICAL EFFICACY FOR TINNITUS MASKING AND TRT**

Although both TRT and tinnitus masking have been in clinical use for over a decade, controlled, prospective studies have not yet been performed to document the clinical efficacy of these techniques. Claims regarding success have been based on analyses of clinical data that have been collected from patients treated with these techniques.

**Outcomes of Tinnitus Masking**

Vernon and Meikle (2000) have summarized studies concerning the long-term clinical effectiveness of wearable masking devices. In their report, they focused on the largest sets of data that had been obtained from tinnitus clinics. In a study of 368 patients who received masking devices in the United Kingdom, questionnaires were administered by the clinical staff 6 months following treatment to determine the effectiveness of the devices (Hazell et al, 1985). Of these patients, 69 percent reported that they were "substantially helped" (helped at least half the time) and 31 percent were "not substantially helped" (helped one-fourth of the time or less). It should be noted that the data collection with respect to the identification of patients who received benefit was retrospective only. There was apparently no comparison of severity indices or handicap indices between the initiation of treatment and the 6-month point.

For patients receiving masking treatment at one US tinnitus clinic located in New York City, Vernon and Meikle (2000) combined data that were reported for four large patient samples, comprising a total of 799 patients (Shulman and Goldstein, 1987; Goldstein and Shulman, 1991, 1996). Each of these patients was advised to purchase masking devices. Of these patients, 356 (45%) actually purchased the masking devices following the 30-day trial period. Using the rationale that patients purchased the devices only if they found them helpful, a success rate of 45 percent was determined for this combined sample.

Vernon and Meikle (2000) also evaluated data obtained from the tinnitus clinic in Oregon, combining data from three successive, nonoverlapping samples of tinnitus patients seen between 1976 and 1989 (Schleuning et al, 1980; Johnson et al, 1989). From this combined sample, 828 patients received recommendations to purchase tinnitus maskers, of which 506 (61%)
patients actually purchased the devices after the trial period. Using the same rationale that a decision to purchase the device(s) is evidence that the device(s) succeeded in producing effective masking, a success rate for this group of patients was determined to be 61 percent.

These various investigations into the efficacy of tinnitus masking have differed greatly regarding the types of devices used, details of the treatment protocols, and criteria for defining success. For example, some clinics used tinnitus instruments (combination hearing aids and maskers) more often than other clinics for their hearing-impaired patients. When applying the use or purchase of wearable tinnitus devices as a criterion for defining success, it would seem important that the treatment protocols include access to the optimum range of devices. It is clear that not all clinics applied the same criteria to the availability and selection of devices. Additionally, purchase of the devices may not necessarily imply or be a reflection of long-term effective tinnitus masking.

These kinds of issues emphasize the importance of establishing standardized treatment protocols and standardized methods for evaluating outcomes of treatment. The above review of outcomes indicates that tinnitus masking may be an effective form of treatment for a large number of tinnitus sufferers attending a tinnitus clinic. Unfortunately, procedures have differed considerably between clinics, and the techniques for identifying efficacious masking devices have not always been conducted to the patient's best advantage (see the previous section on the misconceptions of tinnitus masking). There has further been the lack of standardization for assessing treatment outcome. Tinnitus masking has been well defined in the literature with regard to evaluation of patients and fitting of devices; however, a specific education or counseling protocol has never been described as part of tinnitus masking, nor is there a clearly defined follow-up schedule. Standardization of the tinnitus masking protocol and formal inclusion of a standardized educational or counseling program and follow-up would enable clinics to use universal procedures to treat their patients. Universal outcomes measurement tools would enable the evaluation of treatment efficacy, not only for tinnitus masking but for all forms of tinnitus treatment.

Outcomes of Tinnitus Retraining Therapy

Although there are no controlled studies documenting the effectiveness of TRT, there are several prospective uncontrolled studies in the literature. A number of clinics are consistent in reporting that the technique is significantly beneficial to between 70 and 85 percent of their patients. At one tinnitus and hyperacusis clinic, outcomes data were evaluated for 152 consecutive patients who received treatment for at least 6 months (Jastreboff, 1998). Patients were identified by clinic staff as success cases if they showed at least 20 percent improvement in two of three areas of outcome measures, including the performance of daily activities affected by tinnitus, annoyance owing to tinnitus, and percentage of time of tinnitus awareness. Of the 152 patients, 129 received full treatment with both sound therapy and directive counseling. Of these 129 patients, 81.4 percent showed improvement in their condition according to the success criteria.

At the Sixth International Tinnitus Seminar, held in Cambridge, England, in 1999, six different clinical groups reported clinical data based on the results of their treatment of patients with TRT or methodology based on TRT. Each of these clinical reports is described briefly below. For these reports, the outcomes data were obtained by clinic staff through verbal administration of the TRT interview forms (Jastreboff and Jastreboff, 1999a).

Jastreboff (1999a) reported data from 223 patients who were seen at his clinic. Only patients who had received counseling with sound therapy using either sound generators or hearing aids were used in the analysis. Using the same criteria described above (Jastreboff, 1998), 81 percent of these patients showed significant improvement.

McKinney and colleagues (1999b) conducted an analysis of 182 patients who received treatment. The criterion used for denoting treatment success was a minimum 40 percent improvement in two or more scales evaluating the effects of tinnitus, including annoyance owing to tinnitus, impact of tinnitus on quality of life, tinnitus loudness, and percentage of time aware of tinnitus. All 182 patients received directive counseling related to TRT, of whom 54 received directive counseling only. The remainder also received sound therapy through the use of wearable ear-level sound generators (n = 72) or hearing aids (n = 56). For the counseling-only group, 72.2 percent of the patients showed improvement. For the group that also received treatment with sound generators (set at a just audible level), 75 percent improved. For the group with hearing aids, 60.7 percent improved. Of the various subgroups, 36 patients
received the “truest” form of TRT (i.e., counseling plus sound generators set at the “mixing point”). For these patients, 83.3 percent showed improvement.

Kellerhals (1999) reported data from 120 patients who were treated with a program based on the principles and rules of TRT. After an average of 7 months of treatment, 71 percent of the patients showed improvement in at least two life activities as assessed in the TRT interviews. Sheldrake and colleagues (1999) conducted a study of 224 patients who received full treatment with TRT. Using the 40 percent improvement criteria mentioned above, 83.7 percent of the patients showed significant benefit.

Bartnik and colleagues (1999) evaluated the outcomes of 120 patients treated with TRT. From their caseload of 556 patients, they selected 24 patients at random for each of the five TRT categories (Jastreboff and Jastreboff, 2001) with the requirement that each patient had been treated for at least 12 months. Using success criteria similar to those of Jastreboff (1998), 77.6 percent of the 120 patients showed significant improvement. These data included 24 patients treated primarily for hyperacusis (category 3), of whom 75 percent exhibited improvement. For patients who required counseling only (category 0), 93 percent improved. Category 1 (counseling and sound generators) and category 2 (counseling and hearing aids) patients improved at rates of 83 and 71 percent, respectively. Category 4 patients suffer from the effects of prolonged exacerbation of tinnitus loudness following exposure to sound and are considered to be the most difficult to treat of the five TRT categories. Of the 24 patients in category 4, 16 (67%) met the improvement criteria.

Heitzmann and colleagues (1999) presented the results of 56 patients who had been treated with TRT for 18 months. Although patient improvement criteria were not specified, they were based on the results of the TRT interview (Jastreboff and Jastreboff, 1999a) using the visual analog scales and the assessment of social and family impact. Eighty-four percent of these patients were reported to be “greatly improved.”

Herraiz and colleagues (1999) presented data from 84 patients who received follow-up evaluations after 1 year of treatment. Three outcome measures were used to define success: patient report of improvement (better, worse, no change), the Tinnitus Handicap Inventory (Newman et al, 1998), and a visual analog scale of tinnitus intensity. Patients received either directive counseling alone (37% of cases) or counseling with sound therapy using either wearable ear-level sound generators (37%) or hearing aids (46%). For the group that required counseling only, 93.7 percent showed improvement according to patient report. For the patients who required counseling and sound therapy, improvement was reported by 83.3 percent of the patients with sound generators and by 84.2 percent of the patients with hearing aids. The overall improvement rate was 88.1 percent for the three groups combined.

Because there is no objective means of measuring tinnitus or of evaluating its severity, we must rely completely on patients’ reports before, during, and following treatment to determine if treatment has been successful. Providing incontrovertible proof that TRT is an effective form of treatment in the majority of cases of severe tinnitus would require a controlled, double-blind study. Such a study has not been conducted, nor will such a study ever be done because patients undergoing such treatment (as well as the treatment providers) cannot be blinded to the procedure (Jastreboff and Jastreboff, 2001). There are studies being conducted at the time of this writing that randomize patients into different groups. These studies will, at least, enable comparisons between different forms of treatment in a prospective, randomized, controlled, single-blind format. Currently, however, we must rely on “evidence by consensus.” The clinical reports of TRT efficacy summarized above are certainly not proof that TRT is successful, but they do at least agree that the majority of patients seem to receive significant benefit as a result of treatment. Thus, evidence by consensus is accumulating, lending validity to TRT as a viable treatment technique.

SUMMARY AND CONCLUSIONS

Tinnitus masking and TRT are two methods for the treatment of severe tinnitus that have been used in tinnitus clinics around the world. These methods differ considerably with regard to both their rationale for treatment and their specific treatment protocols. They are alike, however, in that each uses sound therapy as a critical component of treatment. There has been considerable debate within the professional tinnitus community as to exactly how these two methods differ. It may be possible to extract what works best from both techniques to develop a more refined and efficient mode of therapy. The purpose of the present article has been to provide an impartial comparison of the two methods, which will hopefully contribute to a greater
understanding of the various details and nuances that are specific to each method.

For the tinnitus clinician, the outcomes data reported for the two methods are both encouraging and problematic. Although both methods appear to be achieving fairly high success rates, it must be acknowledged that proponents of each method have evaluated their own results, potentially resulting in investigator bias. In addition, these studies differ in many respects, especially in regard to their criteria for determining treatment efficacy. It is thus difficult to compare results both within and between methods. Although various research groups have made substantial efforts to provide quantification of their treatment results, none of these groups has as yet reported treatment outcomes using measurement instruments with consensually accepted statistical properties.

There have been many pleas in the past for tinnitus researchers and clinicians to unify in their approach to clinical management of tinnitus patients. Combining the expertise of tinnitus experts in a unified effort would result in the needed standardization of all aspects of tinnitus management. Standardization is the single greatest need that must be met to establish consistency across clinics and research laboratories. The power that would come from consistent methodology and from unbiased, objective outcomes measurements would be manifested in the ability to combine data across all sites that adhere to the accepted standardization. These data are critically needed to optimally assess the true efficacy of the various techniques that are purported to be beneficial to tinnitus patients.

At present, it is not even known if doing absolutely nothing for the typical tinnitus sufferer will result in adaptation to the tinnitus over a period of years that could be viewed as "substantial improvement." It may be the case that most individuals with incipient tinnitus will learn some sort of adaptive procedures. If one reviews the literature related to tinnitus treatment, there are innumerable claims concerning the positive effects of a variety of treatments. One example of this phenomenon is the numerous reports of the therapeutic effect of ginkgo biloba leaf extracts in the treatment of tinnitus. Because of these reports, many thousands of tinnitus sufferers have self-administered ginkgo biloba for tinnitus relief. Recently, however, a trial was undertaken in a group of 1115 individuals who had experienced tinnitus for at least a year in an attempt to determine definitively if ginkgo provides such therapeutic benefit (Drew and Davies, 1999). In this match-paired, double-blinded, placebo-controlled, randomized trial, the data indicated no greater therapeutic effect of ginkgo biloba than placebo in the treatment of tinnitus. Without such a large, methodologically rigorous trial, no firm conclusions could have otherwise been drawn about the overall effectiveness of ginkgo, and countless sufferers would continue to ingest it with the false hope of attaining relief. In all fairness, however, such generalized results do not preclude the potential usefulness of ginkgo for a yet-to-be-defined subset of individuals. The study results (Drew and Davies, 1999) are not inconsistent with that possibility.

The ginkgo study reinforces the need for, prospective, controlled studies to scientifically evaluate the effects of treatment for tinnitus. Tinnitus masking and TRT have both been shown to be effective but not by rigorous standards. These methods thus appear to be promising for providing significant therapeutic benefit if the methods are conducted properly. Tinnitus clinicians are hindered, however, by the absence of standardized outcomes data on which to base reasonable judgments regarding treatment efficacy. The need is for data from controlled trials with thorough classification of patients, consistent methodology and end points, and long-term follow-up and from which all stages of data acquisition and analysis are rigorous. The result of such studies would be objective data that have been subjected to the peer-review process, both for project funding and for publication of results. The peer-review process is the best means available to ensure that studies are conducted properly and that data are reported accurately. A concerted effort to conduct rigorous outcomes-based tinnitus research will provide the data and standardized procedures that are urgently needed by tinnitus sufferers.

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