
Tinnitus Improvement with Ultra-High-Frequency Vibration Therapy

Barbara A. Goldstein,¹ Martin L. Lenhardt,² and Abraham Shulman¹

¹ Department of Otolaryngology, State University of New York, Downstate Medical Center, Brooklyn, and Martha Entenmann Tinnitus Research Center, Forest Hills, New York, and

² Program in Biomedical Engineering, Virginia Commonwealth University, Richmond, Virginia

Abstract: This study reports on the long-term benefit of ultra-high-frequency masking with the UltraQuiet device. A commercial product, UltraQuiet provides a new form of high-frequency bone conduction therapy. To assess its effectiveness in tinnitus treatment, we selected 15 patients with problematic tinnitus and randomly assigned them to three variations of the medical-audiological tinnitus patient protocol modified for the UltraQuiet study. We assessed tinnitus relief by questionnaires directed at weighing patient response to overall effectiveness, tinnitus loudness, tinnitus severity, and tinnitus annoyance. Additionally, we performed audiological measures (including pure-tone and speech audiometry, minimal masking levels, pitch and loudness matching, and residual inhibition). All patients showed some long-term gains, and most exhibited relief in at least one measurement parameter, providing support for the use of high-frequency vibration in the treatment of tinnitus.

Key Words: high-frequency bone conduction; minimal masking levels; positron emission tomography; tinnitus questionnaires; ultra-high frequency

This study reports on the long-term benefit of ultra-high-frequency masking with the UltraQuiet (UQ) device. Most nonpulsatile tinnitus is characterized as high-pitched. Logically, high-frequency masking should provide effective relief in persons with severe problematic tinnitus. However, such an assumption is valid for only perhaps one-third of tinnitus patients; one possible explanation for the lack of masking in the majority of tinnitus cases is the unavailability of very high-frequency masking energy (<10 kHz). We employed a commercial product, UltraQuiet, which provides a new form of high-frequency bone-conducted masking therapy. To assess its effectiveness in tinnitus treatment, we selected 15 patients with problematic tinnitus and randomly assigned them to three variations of the medical-audiological tinnitus patient protocol [1] modified for the UltraQuiet study [2]. We assessed tin-

nitus relief by questionnaires directed at weighing patient response to overall effectiveness, tinnitus loudness, tinnitus severity, and tinnitus annoyance. Additionally we performed audiological measures (including pure-tone and speech audiometry, minimal masking levels, pitch and loudness matching, and residual inhibition [RI]). All patients showed some gains, and most exhibited relief in at least one measurement parameter, providing support for the use of high-frequency vibration in the treatment of tinnitus.

Well accepted is that if maskers overlap in frequency with the tones to be masked, masking is likely to occur, its degree related to masker intensity. In the case of masking tinnitus by an external noise, this relationship is more the exception than the rule. Tinnitus is not masked as is a tone in many subjects [3–10]. Instead, tinnitus and masking noise may interact in the neuraxis [7]. That is, tinnitus masking may be a complicated product of peripheral and central processes, and sounds outside of traditional psychoacoustic ranges can be effective with tinnitus [2], including ultrasound masking delivered through bone conduction [11]. Growing evidence suggests that high-frequency masking is desirable in cases of high-frequency tinnitus [2,11]. Two

Reprint requests: Barbara A. Goldstein, PhD, Department of Otolaryngology, State University of New York, Downstate Medical Center, 450 Clarkson Avenue, Box 1239, Brooklyn, New York 11203. Phone: 718-773-8888; Fax: 718-465-3669; E-mail: metrc@inch.com

problems exist: One is developing an efficient, commercially viable, and calibratable transducer and the other is determining a reliable clinical-use protocol. In a preliminary report [2], we found a high-frequency tinnitus device, UltraQuiet, to be efficacious. However, we worked with only 9 subjects.

Because tinnitus can usually be masked (at least partially) for some period by a variety of sounds, one commonly used procedure is to assess wide-range masking, termed *minimal masking levels* (MMLs), using a variety of frequencies, including broad- or narrowband noise [12]. The masking stimulus is raised in 5-dB steps, and patients are asked whether their tinnitus is still audible. The intensity level of masking that covers the tinnitus is the MML for that frequency. Not all patients report complete—or sometimes any—masking, even at high-intensity levels. Wearable maskers are helpful for approximately 30% of affected patients [10,13,14]. Thus, for some patients, traditional masking is one option for tinnitus therapy. For many patients, substituting one sound for another is not considered a significant enough improvement; additional relief is desired. The masking stimulation, if properly chosen, may have the capacity of changing how the brain processes tinnitus, which could provide long-lasting benefit. The long-term benefit of UltraQuiet masking is the focus of this study. Often, behavioral measures are contradictory, rendering efficacy determination problematic. An objective assessment measure would help to clarify masker effectiveness [15].

In imaging the brains of a few patients with tinnitus, Muhlnickel et al. [16] revealed a process in which the tinnitus frequency had expanded to more than twice the size in primary auditory cortical space. That is to say, tinnitus dramatically altered the frequency map in the auditory brain. The effect of this expansion on connections to the limbic system and other cortical areas is not known, nor have the tuning characteristics of these “recruited” neurons been measured. If neural space expansion of the tinnitus frequency (or frequencies) is associated with synchronized activity, ignoring an attention-generating tinnitus percept that could readily arise may be impossible. Increased degrees of neural synchrony-dyssynchrony could activate and continue to stimulate the amygdala, an organ known to be critical in evoking emotional and autonomic nervous responses [17].

Theoretically, stimulation above the tinnitus frequency may supplement or assist the neurological reprogramming at the cortex and perhaps restore the normal-frequency spatial relationship. The stimulation must be very high in spectral content to accomplish this above the tinnitus pitch requirement. The UltraQuiet device delivers amplitude-modulated musical-type stimulation in the range of 10–20 kHz suitable for this pur-

pose. Preliminary clinical reports were encouraging [2] and a calibration procedure, anchored to international standards, was followed [18].

METHOD

Goal

The goal of this study was to evaluate the long-term efficacy of using UltraQuiet high-frequency bone-conduction therapy for treating tinnitus, using pre- and postbehavioral assessment of tinnitus loudness, tinnitus anxiety, and tinnitus severity. Additionally, we employed self-reports via questionnaires. We specifically investigated the use of the UltraQuiet device for providing relief, masking, and RI in individuals with problematic tinnitus of the severe disabling type.

Subjects

Fifteen subjects (3 female, 12 male) with subjective idiopathic tinnitus of the severe disabling type participated in the study. All subjects had mild to moderate high-frequency hearing loss. Their age range was 35–72 years (mean, 50.7 years). The pitch match to the tinnitus for 14 of the 15 subjects was high-pitched, matching to either a pure-tone or a narrowband noise or a combination of both, with frequencies between 3 and 16 kHz; 1 subject had a low-pitched tonal tinnitus at 450 Hz.

Stimulus

The intervention consisted of listening to digitally processed music. Music appears to be a more effective tinnitus masker than is noise [19], possibly owing to the involvement of more central and cognitive processes. The stimulus consisted of synthesized music digitally processed and used to modulate a carrier at 16 kHz. We used steep-cutoff, low-pass filters, limiting the upper acoustical frequency range. The carrier was phase suppressed, resulting in a passband from approximately the <10- to 20-kHz range.

The stimulus was produced using Kyma Version 5 software with a Capybara 320 Sound Computation Engine, and it was recorded on a compact disk (CD). The CD recording stimulus consisted of digitally processed music (44.1-kHz sampling rate) with playback in the 10- to 20-kHz range. The CD was played through a custom-made amplifier into a piezoelectric bone-conduction transducer. The spectrum of the high-frequency stimulus is depicted in Figure 1.

The transducer is a custom-made aluminum ceramic bimorph with a high-frequency limit of some 50 kHz.

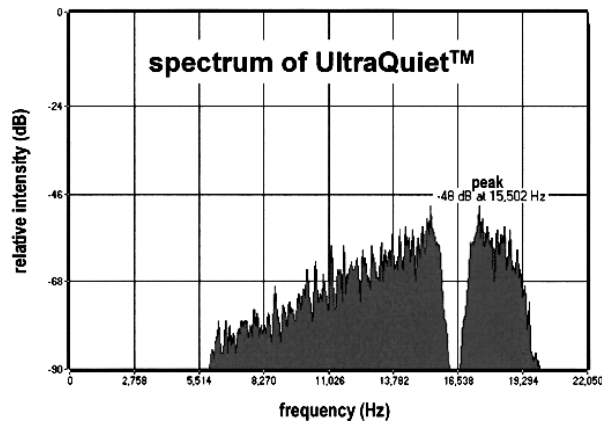


Figure 1. Spectrum of the high-frequency bone-conducted stimulation ranges from approximately 6 kHz to 20 kHz. Most of the energy is in the 10- to 20-kHz range, with 16-kHz phase suppresses.

The transducer is coupled to the skin and held in place with a band, much as are traditional clinical bone-conduction transducers. Some energy occurs around 6 kHz, owing to the transducer's fundamental resonance and the high-pass filter slope. The 6-kHz energy is opportunistic in that it allows calibration of the UltraQuiet system using a Bruel and Kjaer standard artificial mastoid (B&K). The UltraQuiet system has a maximum output of 53 dB hearing level (HL) when it is mass-loaded to the artificial mastoid with 5.4 Newtons of force applied. The transducer was held in place on the mastoid bone of affected subjects by a headband. (Although the stimulus is presented on only one side of the head, it is heard binaurally through bone conduction.) The transducer, headband, and amplifier were all approved by the U.S. Food and Drug Administration prior to use in this study.

The UltraQuiet stimulus parameters, or sound features, were chosen to optimize the activation of auditory cortical neurons. Cortical neurons have been shown to be sensitive to frequency edges, temporal patterns, and frequency or intensity transitions [20]. In other words, features that are found in speech, music, or amplitude-frequency modulation were incorporated into the stimulus to facilitate auditory cortical activation.

Procedure

The study was designed as a pre-post single-subject repeated-measures program. We conducted initial testing before the first session. Audiological evaluation included pure-tone audiometry, speech audiometry, tinnitus pitch and loudness matching, the measurement of RI, and masking curves to establish MMLs at 250–8,000 Hz using both narrowband and white noise. All were part

of the standard audiological procedures previously reported [1,21,22].

Classification of masking curve type according to Feldmann's system was applied to the masking data, and we measured loudness discomfort levels at 250–8,000 Hz. We presented outcome questionnaires to establish a baseline of functioning; these included the tinnitus intensity index, the annoyance index, and the tinnitus severity index [1,21,22]. One week after the last intervention session, we repeated the audiological evaluation and administered the outcome questionnaires to assess any changes. We presented a long-term follow-up questionnaire 8 weeks after the final session.

To assess, in a preliminary fashion, the effects of treatment length, we randomly assigned subjects to one of three groups. Each group consisted of five subjects. Group 1 received stimulation twice weekly for 2 weeks, stopped the stimulation for 2 weeks, then received stimulation twice weekly for 3 weeks, for a total of 10 sessions. Group 2 received stimulation twice weekly for 3 weeks, stopped the stimulation for 2 weeks, then received stimulation twice weekly for 3 weeks, for a total of 12 sessions. Group 3 received stimulation twice weekly for 4 weeks, stopped the stimulation for 1 week, then received stimulation twice weekly for 3 weeks, for a total of 14 sessions.

Before each stimulation session, subjects completed three outcome measurements: the tinnitus intensity index, the annoyance index, and the tinnitus severity index [1]. After each listening session, an individual session evaluation form was completed with respect to changes in tinnitus intensity; presence or absence of RI; duration (if any) of RI; and any other changes or comments. The stimulation lasted 30 minutes for the first session and 1 hour for all succeeding sessions. The bone-conduction transducer was placed on the right mastoid process. The threshold for stimulation was established, and the stimulation was presented 6 dB above threshold or 6-dB sensation level (SL). Although the stimulus is presented on only one side of the head, it is heard binaurally through bone conduction [23]. The protocol was approved by the Western Institutional Review Board.

RESULTS

When 15 patients with problematic tinnitus were questioned as to the effect of UltraQuiet on their tinnitus 1 week and 8 weeks after therapy had ceased, 74.6% (11 patients) indicated a benefit, and approximately half of those (6 patients) indicated that their tinnitus was "moderately or much better." These data are plotted in Figure 2. No one indicated a poorer result, and those four reporting no change in their tinnitus did indicate improvement on measures of tinnitus intensity or severity

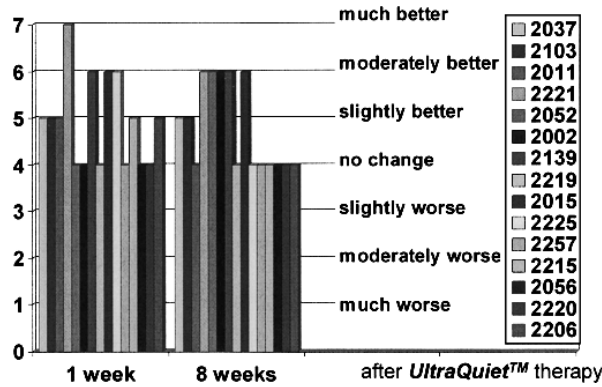


Figure 2. Results of patient questionnaires at 1 and 8 weeks after therapy had ended. Note the general improvement that lasted for 2 months in approximately one-half of the patients.

after therapy treatment. Some patients indicated more improvement than others, but the trend in all patients was an increase in tinnitus relief.

The results of questionnaires addressing tinnitus severity indicated a significant pre- and posttherapy change ($p = .006$; $t = 2.98$) over the course of the UltraQuiet trials. That is, as a group, the patients with problematic tinnitus indicated a significant reduction in severity over the course of the treatment trials. Tinnitus severity improvement for the group was evident at the second session, gradually increasing through the twelfth session. Further improvement may be present but is obscured by the duration parameters of the three groups. That is, for the latter sessions, the number of patients being tested dropped, owing to the session limitations for each of the three treatment groups.

The questionnaire results for measures of tinnitus in-

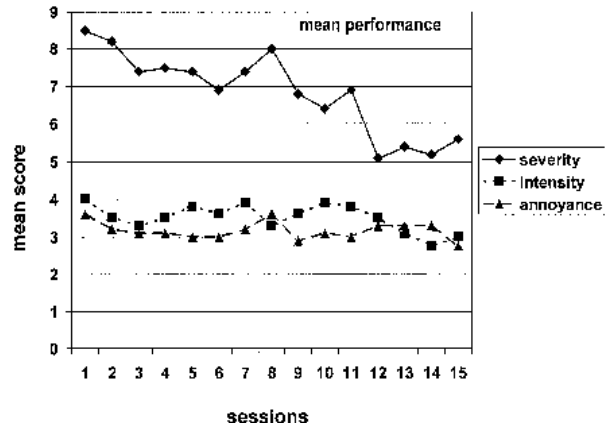


Figure 3. Effects of high-frequency therapy on three outcome measures—tinnitus severity, intensity, and annoyance—as evaluated by questionnaires completed after each therapy session. Clearly the severity is decreasing, with a trend in that direction for anxiety and loudness.

tensity and annoyance were not significantly different over the course of therapy sessions, although a drop in the mean level for each was noted on the last few trials. The mean intensity questionnaire score fell from 5 to 4 over 15 sessions, whereas the annoyance mean score fell from 3.6 to 2.76 points. These mean data are plotted in Figure 3. Taken as a whole, group averages suggested tinnitus relief in the behavioral indices.

MML change proved to be the most robust effect of high-frequency tinnitus therapy. For some patients at some frequencies, reductions in MMLs were as high as 25–45 dB in one ear (Fig. 4). The mean data are perhaps as revealing; when patient and ear data are collapsed, a high-frequency reduction in masking is observed (Fig. 5).

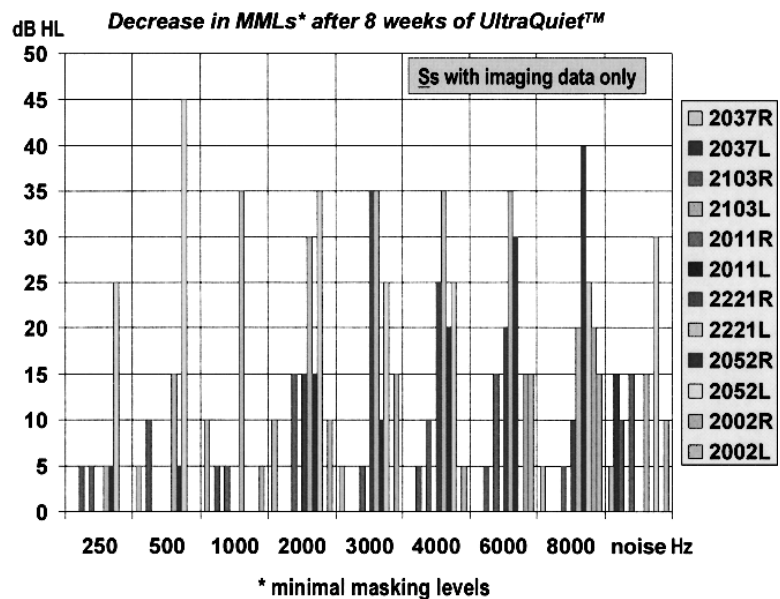


Figure 4. Decrease in the minimum masking levels (MMLs) for the six patients who received brain imaging before and after therapy. Variability is seen, but a clear change after therapy is evident.

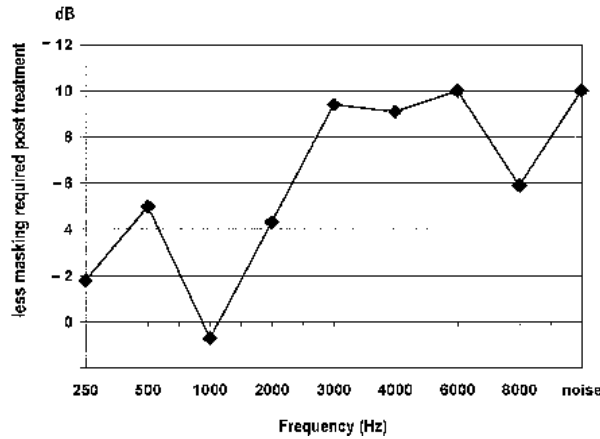


Figure 5. Mean minimum masking levels for all subjects when patient and ear data are collapsed reveals a frequency-specific pattern. High-frequency therapy generally results in less masking for the higher frequencies.

The frequency area that exhibited the greatest effect is the octave from 3 to 6 kHz, below the lowest resonance in our transducer (6 kHz). Stated another way, the frequencies that required less energy to mask tinnitus were those just below the lowest effective stimulating frequencies in the UltraQuiet system. These frequencies were on the edge of the patients’ audiometric hearing loss, a region often associated with increased discrimination possibly due to neural plasticity [24,25]. The MML improvement was related to the measured tinnitus pitch in that both were high-frequency (with one pitch match exception).

We examined the relationship among high-frequency MMLs, tinnitus pitch, tinnitus intensity, and Feldmann masking curves. Individual variability in this small sample of patients with problematic tinnitus precluded any detailed analysis, but tinnitus intensity ratings exceeding 50 dB were associated with improvement on the overall tinnitus relief questionnaire and were associated with a high-frequency pitch match. The tinnitus pitch match most frequently occurred in the region of the hearing loss but not necessarily at the frequency with the maximal loss. For some, the tinnitus pitch match was near the edge of normal hearing and hearing loss. No consistent pattern was noted between Feldmann masking curve type and tinnitus pitch match (Fig. 6).

No subjective loss of hearing was reported by any patient during therapy. Figure 7 identifies thresholds that fluctuated for some frequencies for some patients. Overall threshold dynamics seemed generally to improve using as the expected variance a criterion of ± 5 dB (0.25–8 kHz) and ± 10 dB for frequencies greater than 8 kHz [26,27]. Although we saw an increase in some thresholds in some patients, twice as many thresholds improved as those that decreased. For the group, hearing improved after high-frequency bone conduction therapy (see Fig. 6).

Six of the 15 patients reported RI during the sessions; for those who so indicated, the mean RI was 5.1 minutes (range, 4.5–6.2 min). Threshold was established before each session but, given the problems in detecting a stimulus in the presence of tinnitus (even in skilled hands), the level of UltraQuiet therapy may have been as little as 2–3 dB SL for some patients in some sessions.

patient	minimal masking levels changes by frequency (kHz)									pitch	loud	FMC
	0.25	0.5	1	2	3	4	6	8	noise			
2103R	-5	-10	-5	0	0	-5	-5	0	-10	6	68	I
2103L	0	0	0	0	0	0	0	0	0			
2011R	0	-5	-5	-15	-5	-10	-15	-5	-15	8	58	IV
2011L	0	0	0	0	0	0	0	0	0			
2221R	10	5	-15	-35	-25	-20	-10	-10	0	0.45	32	IV
2221L	-5	-15	-35	-30	-35	-35	-20	-15				
2052R	-10	-15	-10	-15	-10	-20	-20	-25	0	8	42	IV
2062L	-25	-35	-45	-35	-25	-25	-10	-40	-30	8	39	
2002R	25	15	10	10	5	0	-15	-20	0	6	52	I
2002L	0	0	-5	-10	-15	-5	-15	-15	-10	6	59	I
2257L	-5	-10	-10	-10	-25	-15	-5	-15	-15	3.15	43	I
2257R	0	0	0	0	0	0	0	0	0			
2206R	-10	-5	-25	-20	15	15	15	-10	0	10	67	IV
2206L	15	20	65	70	35	35	25	30	0	10	60	IV
2225R	-20	-5	25	5	15	0	-5	5	0	3	9	I
2225L	0	0	0	0	0	0	0	0	0			
2139R	-5	10	0	-20	-25	10	-25	20	10	8	20	I
2139L	-20	-15	-10	-20	-5	-5	-5	-25	5	6	22	IV
2215R	15	10	15	15	0	5	5	10	0	7	77	I
2215L	0	0	0	0	0	0	0	0	0			
2220R	-20	-20	5	25	10	10	10	10	0	3	30	I
2220L	-15	-10	-15	0	0	-5	-5	0	-10	3	33	I
2219R	10	10	15	15	10	5	30	15	0	8	2	I
2219L	-15	-10	10	5	10	5	0	5	0	6	12	IV
2015R	15	-20	-10	10	-15	-10	-5	15	0	6	60	I
2015L	-10	-25	-15	-50	-15	10	-5	0	0	5	60	I
2036R	5	0	-5	-10	-5	-5	-10	-20	0	8	38	IV
2036L	0	0	0	0	0	0	0	0	0			
2037R	0	5	-10	-10	5	0	0	-5	-5	16	112	IV
2037L	5	0	0	0	0	0	0	0	-15	16	109	IV

Figure 6. Relationship among minimal masking level changes (by frequency), Feldmann masking curve (FMC) types, and pitch and loudness matches in all subjects.

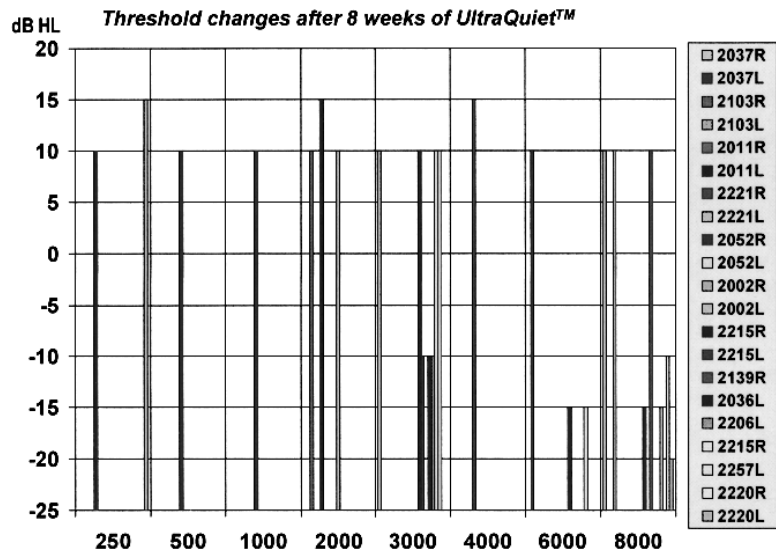


Figure 7. Hearing thresholds before and after therapy generally suggest improvement after therapy; however, the pattern was complex and included elevation in some frequencies. Dynamic hearing levels appear related to central processes assumed to be active during and after therapy.

Individuals received 10-, 12-, or 14 sessions of therapy. Patients in the 10-session group averaged just above “no change,” whereas those in the 12- and 14-session groups averaged above “slight improvement.” What must be emphasized is that these patients with problematic tinnitus have had limited therapeutic success with other treatment modalities. Note in Figure 3 that dramatic improvement in tinnitus severity occurs in session 12, as does a modest abatement of tinnitus intensity and annoyance.

DISCUSSION

The use of high-frequency bone conduction stimulation using the UltraQuiet therapy system resulted in long-term reduction in tinnitus severity during therapy, and that tinnitus relief lasted for at least 2 months after therapy in most subjects in this study. The tinnitus relief was inferred from a pattern of lower weekly scores on the tinnitus severity scale and reduction in MMLs. Four factors likely contributed to long-term tinnitus relief: ultra-high-frequency masking, RI, neurological reprogramming, and habituation.

During posttherapy interviewing, we noted partial masking of the tinnitus by the UltraQuiet system throughout the trial in all patients (although not in every session). Owing to stringent adherence to the protocol approved by the Western Institutional Review Board, we made no effort to increase the stimulation level in an attempt to produce complete masking. The strategy of using high frequencies at low levels was designed to potentially provide some partial masking but, more important, was designed to aid in tinnitus neurological reprogramming and habituation. Nonetheless, the frequency

range of masking is important in obtaining neurological reprogramming and inhibition [16,18].

Masking high-frequency tinnitus is possible with lower frequencies (<4 kHz), but that approach most frequently is less efficient in that the frequency mismatch must be overcome by increasing the intensity. Exceptions exist and are evident from Feldmann masking-curve data [12]. What the Feldmann masking curve indicates is whether tinnitus can be masked and the levels needed at discrete frequencies to mask the tinnitus. All our 15 subjects had either type 1 or type 4 curves. Those with type 1 curves are good candidates for traditional ear-level masking devices. However, patients with type 4 curves, although they can be masked, usually do not find traditional maskers a relief because of the intensity level necessary to provide masking. The result can be masking relief, but hyperacusis and speech interference often are byproducts. Given the uncertainty of how tinnitus is masked in the central nervous system, choosing sounds that overlap with the tinnitus frequency seems prudent for long-term relief. The role of Feldmann masking curve type and long-term relief for problematic tinnitus patients requires further investigation.

Frequency range of stimulation is critical in the auditory cortical reprogramming approach of the UltraQuiet system; however, any reduction in the amount of masking required to eliminate (or partially eliminate) tinnitus also is important. Vernon and Meikle [10,28] concurred that low MMLs (< 15 dB) likely contribute to the success of masking as long-term therapy. We agree but would add that if initial MMLs are high and high-frequency stimulation is applied (which lowers MMLs), tinnitus relief also is possible. Of particular interest is the high-frequency MML effect. Improvement

in MMLs (i.e., less energy required to mask tinnitus) is parsimonious with changes in the tinnitus modified-frequency map in the primary auditory cortex.

Alternatively, we could argue that the energy around 6 kHz was predominant in our subjects owing to mild to moderate sensorineural hearing loss. All patients had serviceable hearing to 12 kHz, but hearing improvement may have been related to relative frequency sensitivity of the UltraQuiet stimulus. This is suggested by the six cohort patients in whom positron emission tomography scans were obtained. Those patients with the best thresholds beyond 10 kHz exhibited the best behavioral and physiological activity [15]. If high-frequency stimulation is essential for auditory cortical reprogramming, the sensitivity to such stimulation should be an essential variable. Thus, the measurement of ultra-high-frequency audiometric thresholds (10–20 kHz) seems essential in establishing the SL of high-frequency tinnitus therapy (i.e., affected patients must hear it) [15,21]. The UltraQuiet masking mechanism appears to be different when using conventional audiological masking at 250–8,000 Hz than when using ultra-high frequencies. With ultra-high frequency, the stimulus is apparently combined with neurological reprogramming and plasticity involving the auditory cortex.

For patients with severe deafness, ultrasonic tinnitus therapy should be considered [29]. It should provide the highest peripheral frequency stimulation possible [30]. High-frequency stimulation, both in the high audio-frequencies (UltraQuiet) [2] and in ultrasonic frequencies [11], have resulted in RI.

RI, which refers to a decrease in the perceived intensity of the tinnitus for a time after the masking stops, was first reported by Feldmann [12]. In an individual with hearing loss and tinnitus, RI may last for a few seconds or minutes but can last days or weeks [2,31]. We observed (by interview at the end of therapy but not by formal testing) RI lasting approximately 5 minutes. RI was present in six of the patients, yet all showed a reduction in tinnitus severity. What should be noted is that the stimulating intensity was only 6 dB SL, and this may not have been sufficient energy to elicit RI in the other patients, a metric to be systematically studied in the future. Annoyance and tinnitus intensity seemed to persist in most throughout the sessions, suggesting that the tinnitus, while reduced in severity, was still present. Terry et al. [32] concluded that a dependence of RI on masker characteristics existed (such as center frequency, bandwidth, and intensity). RI increased with masker intensity, but the relationship of RI to tinnitus frequency, masker center frequency, and bandwidth was complex and varied among individuals.

The use of RI as a predictor of tinnitus relief, while common, may not be adequate. The acceptance of RI

over questionnaire data is understandable in an effort to obtain a more “physiological” metric. The conclusion of Shulman [15] suggests that a brain-imaging index in conjunction with high-frequency audiometry may be the technique of choice in objectively assessing tinnitus relief from auditory therapy if neurological reprogramming and habituation are the essential processes as hypothesized.

The suggestion by Muhnckel et al. [16] that the tinnitus frequency map expands in the primary cortex and this increased representation influences the response of the medial temporal lobe system is very consistent with the behavioral parameters of tinnitus observed in our study. Cortical reprogramming as a consequence of sensorineural hearing loss has been well established [33, 34]. High-frequency hearing loss often is associated with high-pitched tinnitus [1]. If the auditory cortex has reprogrammed, stimulation with very high frequencies might stabilize and reverse the process and perhaps restore the normal frequency map. Cortical potentials, in the region of the tinnitus frequencies, are also abnormal [35]. High-frequency stimulation with the UltraQuiet passband of 10–20 kHz has the added quality of disrupting the tinnitus frequency synchrony and reducing the overrepresentation, which might be verified with cortical potentials.

Because the UltraQuiet stimulus generally overlaps with high-frequency tinnitus and the presentation is just above threshold stimulation (~6 dB SL), inhibition should be facilitated. What effect the increase in stimulation level from 6 dB SL to 12 dB SL would have on the effect of masking, on further reduction in MMLs, and on increased RI remains to be explored. In view of the degree of improvement and results with the limited number of sessions in our study, a reasonable expectation is improved results with an increased level of stimulation (12 dB SL) and an increased number of sessions over time. The question of the minimal number of trials needed to note tinnitus relief, given that choices were limited to 10, 12, and 14 sessions, can be answered only by stating that 10 session of therapy (and probably fewer) are not as effective as 12 and 14 sessions, on the basis of questionnaire results after therapy. According to these serial measures, therapy of fewer than 12 sessions would not be as satisfactory as therapy lasting 12 and 14 sessions.

Treating tinnitus patients with the UltraQuiet device is more difficult when their tinnitus is of the severe problematic type. When contrasted to normal controls and tinnitus patients who tolerate their tinnitus, patients with problematic tinnitus showed less habituation in middle latency potentials [36]. Additionally, auditory brainstem response differences between tinnitus patients and controls further suggest that auditory path-

way transmission may influence abnormal habituation. Patients with problematic tinnitus appear not to exhibit normal habituation, and this can influence their perception of tinnitus loudness. Tinnitus loudness and annoyance remained stable throughout most of the therapy sessions. In the normal auditory system, an increase in loudness is related to an increase in neural activity. Patients who do not exhibit normal habituation and who rate their tinnitus as loud may have more active dyssynchronous neurons involved in tinnitus perception than do patients who assess their tinnitus loudness as low. Such a situation would be predicted in the tinnitus frequency map expansion in the auditory cortex and would influence both the medial temporal lobe system and other cortical area identified as active in tinnitus [37].

Problematic tinnitus is most likely related to changes in the auditory pathway and consequent reactions in various areas of the brain. The emerging picture is that of an initial insult to the ear or brain (or both) followed by an increase in the tinnitus frequency cortical map, which could increase dyssynchrony-synchrony and loudness and reduce habituation. Such a condition could hyperactivate the medial temporal and prefrontal lobes, resulting in problematic tinnitus characterized by annoyance, and could trigger autonomic reactions. Although we readily recognize that the neural substrate of problematic tinnitus encompasses much more than the auditory pathway, the role of the auditory pathway in masking, RI, neurological reprogramming, and habituation is significant [37]. A plastic auditory pathway treated with a stimulus specifically designed for high-pitched tinnitus may, with time, provide long-term relief. The changes in MMLs and auditory thresholds suggest an adaptive central nervous system, responsive to high-frequency sound therapy. Long-term tinnitus relief cannot be solely defined by one metric as complete masking or RI on the order of hours. Relief is a complex function of many factors arising both within and outside the auditory system, and successful treatment takes time. Brain imaging and high-frequency audiometrics seem to be important indices in quantifying tinnitus relief.

ACKNOWLEDGMENT

The authors acknowledge the support of Sound Technique Systems, LLC, in this study and the assistance of Robert Guinta.

REFERENCES

1. Shulman A, Tonndorf J, Feldmann H, et al. *Tinnitus: Diagnosis/Treatment*. Philadelphia: Lea & Febiger, 1991.

2. Goldstein BA, Shulman A, Lenhardt ML, et al. Long-term inhibition of tinnitus by UltraQuiet therapy: Preliminary report. *Int Tinnitus J* 7:122–127, 2001.
3. Goldstein BA, Shulman A. Tinnitus Masking—A Longitudinal Study of Efficacy/Diagnosis 1977–1994. In GE Reich, JA Vernon (eds), *Proceedings of the Fifth International Tinnitus Seminar 1995*. Portland, OR: American Tinnitus Association, 1991:315–321.
4. Warren RM. *Auditory Perception: A New Analysis and Synthesis*. New York: Cambridge University Press, 1999.
5. Shailer M, Tyler RS, Coles RRA. Critical masking bands for sensorineural tinnitus. *Scand Audiol* 10:157–167, 1980.
6. Tyler RS, Conrad-Arnes D, Smith, P. Postmasking effects of sensorineural tinnitus: A preliminary investigation. *J Speech Hear Res* 27:466–474, 1984.
7. Penner MJ. Masking of tinnitus and central masking. *J Speech Hear Res* 30:147–152, 1987.
8. Smith PA, Parr VM, Lutman ME, Coles RRA. Comparative study of four noise spectra as potential tinnitus maskers. *Br J Audiol* 25:25–34, 1991.
9. Kitajima K, Kitahara M, Kodama A. Can tinnitus be masked by band erased filtered masker? Masking tinnitus with sounds not covering the tinnitus frequency. *Am J Otol* 8:203–206, 1987.
10. Vernon JA, Meikle MB. Tinnitus Masking. In RS Tyler (ed), *Tinnitus Handbook*. San Diego: Singular, 2000:313–355.
11. Meikle MB, Edlefsen LL, Lay JW. *Suppression of Tinnitus by Bone Conduction of Ultrasound*. Poster presented at the Twenty-First Annual Meeting of the Association for Research in Otolaryngology, 1999.
12. Feldmann H. Homolateral and contralateral masking of tinnitus by noise bands and pure tones. *Audiology* 10: 138–144, 1971.
13. Vernon J, Griest S, Press L. Attributes of tinnitus and the acceptance of masking. *Am J Otolaryngol* 11(1):44–50, 1990.
14. Vernon JA, Meikle MB. Tinnitus: Clinical measurement. *Otolaryngol Clin North Am* 36(2):293–305, 2003.
15. Shulman A, Strashun AM, Avitable J, et al. Ultra-high-frequency acoustic stimulation and tinnitus control: A positron emission tomography study. *Int Tinnitus J* 10(2): 113–125, 2004.
16. Muhlnickel W, Elbert T, Taub E, Flor H. Reorganization of auditory cortex in tinnitus. *Proc Natl Acad Sci USA* 95: 10340–10343, 1998.
17. Wilensky AE, Schafe GE, LeDoux JE. Functional inactivation of the amygdale before but not after auditory fear conditioning prevents memory formation. *J Neurosci* 19(24):RC48, 1999.
18. Lenhardt ML, Richards DG, Madsen AG, et al. Measurement of bone conduction levels for high frequencies. *Int Tinnitus J* 8(1):9–12, 2002.
19. Al-Jassim AH. The use of Walkman mini-stereo system as a tinnitus masker. *J Laryngol Otol* 102(1):27–28, 1988.
20. de Charms RC, Blake DT, Merzenich MM. Optimizing sound features for cortical neurons. *Science* 280(5368): 1439–1443, 1998.

21. Shulman A, Strashun AM, Avitable MA, et al. *Ultra-High-Frequency Stimulation and Tinnitus Relief*. Presented at the Thirty-First Congress of the Neurootological and Equilibriometric Society, Bad Kissingen, Germany, March 25–27, 2004.
22. Shulman A. Medical audiological evaluation of the tinnitus patients. *Semin Hear* 8(1):7–14, 1987.
23. Cai Z, Richards DG, Lenhardt ML, Madsen AG. Response of human skull to bone-conducted sound in the audiometric-ultrasonic range. *Int Tinnitus J* 8(1):3–8, 2002.
24. Thai-Van H, Micheyl C, Norena A, Collet L. Local improvement in auditory frequency discrimination is associated with hearing-loss slope in subjects with cochlear damage. *Brain* 125(3):524–537, 2002.
25. McDermott HJ, Lech M, Kornblum MS, Irvine DR. Loudness perception and frequency discrimination in subjects with steeply sloping hearing loss: Possible correlates of neural plasticity. *J Acoust Soc Am* 104:2314–2325, 1998.
26. Schmuziger N, Probst R, Smurzynski J. Test-retest reliability of pure-tone thresholds from 0.5 to 16 kHz using Sennheiser HDA 200 and Etymotic Research ER-2 earphones. *Ear Hear* 25(2):127–132, 2004.
27. Frank T. High-frequency (8 to 16 kHz) reference thresholds and intrasubject threshold variability relative to ototoxicity criteria using a Sennheiser HDA 200 earphone. *Ear Hear* 22(2):161–168, 2001.
28. Vernon JA, Meikle MB. Masking devices and alprazolam treatment for tinnitus. *Otolaryngol Clin North Am* 36(2):307–320, 2003.
29. Lenhardt, ML. Ultrasonic hearing in humans: Applications for tinnitus treatment. *Int Tinnitus J* 9:2, 2003.
30. Lenhardt ML, Skellett R, Wang P, Clarke AM. Human ultrasonic speech perception. *Science* 253:82–85, 1991.
31. Hazell, JWP, Wood S. Tinnitus masking—a significant contribution to tinnitus management. *Br J Audiol* 15:223–230, 1981.
32. Terry AMP, Jones DM, David BR, Slater R. Parametric studies of tinnitus masking and residual inhibition. *Br J Audiol* 17:245–256, 1983.
33. Engineer ND, Percaccio CR, Pandya PK, et al. Environmental enrichment improves response strength, threshold, selectivity, and latency of auditory cortex neurons. *J Neurophysiol* 92(1):73–82, 2004.
34. Lee CC, Schreiner CE, Imaizumi K, Winer JA. Tonotopic and heterotopic projection systems in physiologically defined auditory cortex. *Neuroscience* 128(4):871–887, 2004.
35. Weisz N, Voss S, Berg P, Elbert T. Abnormal auditory mismatch response in tinnitus sufferers with high frequency hearing loss is associated with subjective distress level. *BMC Neurosci* 1186(1471):2202–2208, 2004.
36. Gerken GM, Hesse PS, Wiorkowski JJ. Auditory evoked responses in control subjects and in patients with problem-tinnitus. *Hear Res* 157(1–2):52–64, 2001.
37. Shulman A. A final common pathway for tinnitus-medial temporal lobe system. *Int Tinnitus J* 1(2):115–126, 1995.