

# Ultra-High-Frequency Ultrasonic External Acoustic Stimulation for Tinnitus Relief: A Method for Patient Selection

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**Abstract:** We proposed a method for patient selection and application of criteria for predicting success with bone-conduction external acoustic stimulation using high-audio-frequency sound in the ranges of 10–20 kHz and 20–26 kHz for individuals with subjective idiopathic tinnitus (SIT) of the severe disabling type. Ultra-high-frequency (UHF) stimulation for tinnitus relief has been found to be most effective when residual neuronal function exists in the acoustic ranges of 10–14 kHz, with thresholds no greater than 40–50 dB sound pressure level (SPL). Ultrasonic (US) acoustic stimulation is recommended for patients with audiometric thresholds greater than 50–60 dB SPL for frequencies of 10–14 kHz. Fifty-two consecutive patients seen for the primary complaint of SIT of the severe disabling type received a trial of either UHF or US bone-conduction acoustic stimulation. Tinnitus relief was reported in 22 of the 52 patients. The application of criteria for patient selection predicted tinnitus relief in 20 of the 22.

**Key Words:** brain plasticity; high-audio-frequency stimulation; ultra-high frequency; ultrasonic

This study reports on a method for patient selection for the use of external bone-conduction acoustic stimulation using high-audio-frequency stimulation with ultra-high-frequency (UHF) sound in the range of 10,000–20,000 Hz and with ultrasonic (US) high-frequency sound in the 20,000- to 26,000-Hz range for individuals with subjective idiopathic tinnitus (SIT) of the severe disabling type. High-frequency stimulation has proved to be effective in tinnitus treatment, presumably owing to neuro-reprogramming rather than simple masking [1].

The first step in providing efficient tinnitus treatment has been hypothesized to be patient selection. Accurate patient selection—or, more precisely, patient matching to the high-pitch tinnitus treatment modality

(UHF or US) for individuals with severe disabling tinnitus—can result in long-term inhibition of tinnitus by external bone-conduction acoustic stimulation with sound in the ranges of 10–20 kHz and 20–26 kHz [2].

UHF-US external acoustic stimulation is available commercially from two devices that have been reported to provide significant relief of severely disabling tinnitus [3,4]. Shulman et al. [5] stated that the subjective behavioral response for tinnitus relief using UHF external acoustic stimulation with the UltraQuiet (UQ) device reflects a dual effect. One is acoustic stimulation of the residual peripheral neuronal function in the UHF range of 10–14 kHz and audiometric thresholds of 40–50 dB sound pressure level (SPL). A second is the integrity of the brain cortex for neuronal reprogramming as demonstrated in metabolic activity seen in positron emission tomography (PET) of brain. A PET of brain study identified a correlation between the UHF audiograms, the subjective reports and outcome measures of the efficacy of the UHF-UQ for tinnitus relief, and brain PET metabolic categories. Specifically, the best

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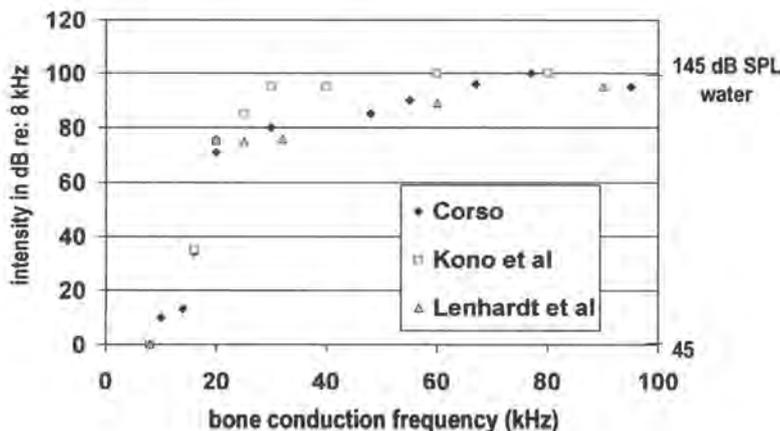
subjective reports for tinnitus relief with UHF were reported by tinnitus patients with auditory thresholds of 40–50 dB SPL or less for the frequency range of 10–14 kHz.

For UHF-US external acoustic stimulation to be most effective, responses must be positive at 10–14 kHz. Hearing thresholds must be no greater than 40–50 dB SPL at 10–14 kHz. That is, patients must be able to hear or respond to the high frequencies. Some individuals with UHF thresholds of greater than 60 dB SPL in the 10- to 12-kHz range have obtained tinnitus relief of varying degrees after receiving US stimulation (i.e., more energy to overcome the mass loading of the head on the vibrator and more energy to stimulate fewer remaining neurons to fire, resulting in plasticity at the cortex). In other words, the minimal residual neuronal responses necessary for obtaining tinnitus relief with UHF external acoustic stimulation require a threshold no greater than 60 dB SPL at 10–14 kHz.

The dilemma of energy needed to hear can be seen in Figure 1. It simply takes more energy to drive vibration through a vibrator mass loaded by the head. To be detected by the human ear, US frequencies must be approximately 100 dB more intense than thresholds at 8 kHz. In contrast, thresholds at 12–14 kHz are only 10–15 dB above thresholds at 8 kHz. Clearly, less energy is required for detection in the high audio range. Typically, bone-conduction levels are referenced to force. Because force is equal to mass times acceleration, the amount of energy needed to move the mass of the head (15 kg) increases with frequency. The situation is more complicated for bone-conduction hearing. In that case, the formula for force is

$$F = |Z| \times A/\omega$$

- where F = force in Newtons (N)
- A = acceleration (referenced to 1 m/sec<sup>2</sup>)
- |Z| = mechanical point impedance (Ns/m)
- ω = angular frequency (radians/sec).



**Figure 1.** Human hearing by bone conduction as depicted by three investigators. Because calibration procedures were different, thresholds at 8 kHz served as a reference such that all thresholds for higher frequencies are in decibels above it. Note that ultrasonic frequencies are 80–100 dB above the thresholds at 8 kHz, whereas high audio frequencies are much lower. (SPL = sound pressure level.)

Because the amount of energy increases proportional to frequency given a constant mass (head) to be detected by the ear, patient UHF hearing would appear to be a valuable parameter in predicting success in tinnitus treatment.

## PATIENTS AND METHOD

### Goal

The goal of this study was to present the results of the application of criteria for predicting success with a bone-conduction external acoustic stimulus using either UHF or US ranges in providing relief for patients with tinnitus of the severe disabling type. We based patient selection criteria on test results from the audiometric data of UHF audiograms. In this review, we included patients presenting with the primary complaint of tinnitus and identified as having tinnitus of the severe disabling type.

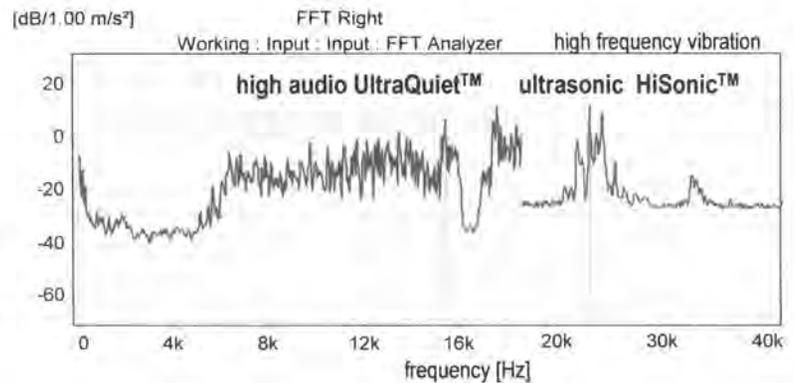
### Stimuli

We administered two types of high-audio-frequency stimuli: either ultra-high-audio-frequency stimulation from 10 to 20 kHz by the UltraQuiet device or low-frequency US from 20 to 26 kHz by the HiSonic device. The spectra of these two devices are presented in Figure 2. The output intensity is measured in acceleration (referenced to 1 m/sec<sup>2</sup>) in regard to the foregoing formula. In each case, a transducer is placed on the mastoid, and the stimulation level is ascertained by determining sensation level.

### Patients

We included in this study 52 consecutive patients (20 women, 32 men; age range, 30–74 years; mean, 56 years) seen for the primary complaint of SIT of the

**Figure 2.** Tinnitus treatment stimuli for the UltraQuiet device (left panel) and the ultrasonic HiSonic device (right panel). Both used amplitude modulation; however, the HiSonic is spectrally narrower and perhaps an octave higher. Intensity is referenced to acceleration ( $1 \text{ m/sec}^2$ ), but no effort was made to equate the two in terms of equivalent output. (FFT = fast Fourier transform.)



severe disabling type. We administered trials of either UHF or US bone-conduction acoustic stimulation.

### Procedure

All patients had completed the medical-audiological tinnitus patient protocol [6,7]. We conducted UHF audiometry using both air-conduction high-frequency audiometry (HFA) with the Beltone 2000 audiometer and electrical HFA (EHFA) with the Tonndorf audiometer. We measured thresholds from 10,000 to 20,000 Hz. After application of the proposed criteria, we selected UHF-US external electrical stimulation for trials to provide tinnitus relief. Each individual received a trial of either UHF or US bone-conduction stimulation for 0.5 to 1 hour [1]. Pitch matching and Feldmann masking curve data were not informative in establishing a criterion for patient selection. Classic acoustic stimulation audiograms measuring 250–8,000 Hz revealed individual variations in hearing thresholds similar to those reported for the total cohort of 15 patients in the UHF-UQ study [8].

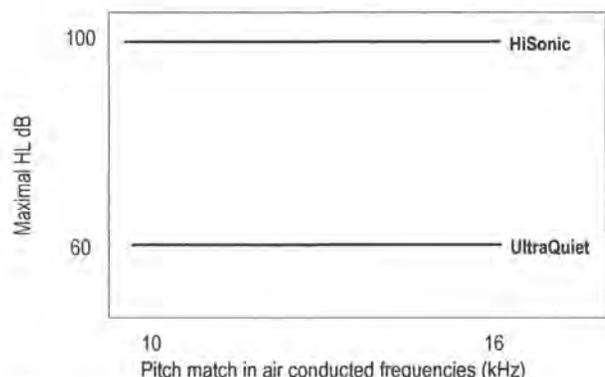
For UHF testing using EHFA, we measured thresholds at 1,000–20,000 Hz at 1,000-Hz intervals in 5-dB steps ranging from 0 dB SPL to a maximum of 60 dB SPL. Thresholds represent binaural response. For HFA using air conduction, we measured thresholds at 10,000–20,000 Hz in 1,000-Hz intervals in 5-dB steps ranging from 0 to 120 dB SPL. In EHFA, the head is capacitively coupled into a circuit, and audio tones are amplitude-modulated on a 60-kHz carrier. With demodulation, owing to the nonlinearities of the skin, tones are perceived as conventional audiometric tones. The thresholds are actually first established in electrical terms and then are converted to an equivalent SPL. The conversion algorithm favors an accurate depiction of frequencies above 8 kHz and was an ideal instrument for assessing bone-conduction thresholds for this study. Thresholds are established for each ear separately, as EHFA is not a binaural phenomenon typical of conventional bone-conduction hearing.

Of 52 consecutive patients who received UHF-US stimulation for relief of SIT of the severe disabling type, 22 reported tinnitus relief. The application of the criteria for patient selection predicted tinnitus relief in 20 of the 22. The patients who reported success with UHF-US fulfilled the audiometric criteria as mentioned earlier.

### DISCUSSION

The application of either high-frequency tinnitus treatment device is summarized in Figure 3. The UltraQuiet is approved by the U.S. Food and Drug Administration for treating individuals with less than 60 dB HL in the high frequencies and to operate at just above threshold. In contrast, the HiSonic has the energy to reach even those with severe deafness. In terms of stimulation, both operate within the range associated with high audio pitch.

Part of the US pitch judgment variability may be related to the process of hearing US. The brain is set into resonance by US (i.e., the brain demodulates US into the high audio frequencies—greater than 15 kHz—like



**Figure 3.** Maximum hearing level (HL) for each device. For patients with high-frequency thresholds above 60 dB, the HiSonic is recommended, whereas for better high-frequency hearing, the UltraQuiet is the tinnitus instrument of choice.

a sphere oscillating). The ear detects the high-frequency sound by bone conduction. US can be cancelled when it must pass through the skull, which has many vibratory antiresonances. Less energy is required at a resonance, more at an antiresonance. The human resonance pattern varies considerably, which is a product of its geometry. Furthermore, US is typically one-half of a full octave above the brain resonances, thus requiring more energy to demodulate the brain. Consequently, more energy is required to hear US than is needed to hear high audio frequencies, although they share the same place of displacement on the basilar membrane [9].

What is interesting to note is that individuals with severe deafness and some high-frequency hearing report US as high-pitched. Individuals with no measurable high-frequency hearing will report US as the quality of the highest pitch they possess. Thus, the place of stimulation in the cochlea ultimately maps the pitch [10].

Classic acoustic stimulation audiograms measuring 250–8,000 Hz do not predict success with high-audio-frequency stimulation or degree of tinnitus relief to be obtained. In our experience, the UHF audiogram is predictive of success with bone-conduction external acoustic stimulation using high audio frequency.

## CONCLUSIONS

UHF for tinnitus relief has been found to be most effective when residual neuronal function exists in the acoustic ranges of 10,000–14,000 Hz, with thresholds no greater than 40–50 dB HL. US acoustic stimulation is recommended for patients with audiometric thresholds of 50–60 dB HL for frequencies of 10,000–14,000 Hz. UHF-US external acoustic stimulation is recommended for attempting tinnitus relief in a selected tinnitus population with thresholds no greater than 50–60 dB SPL in the 10,000- to 14,000-Hz ranges.

Of 52 consecutive patients for whom high-audio-frequency stimulation using UHF or US was recom-

mended for attempting tinnitus relief, 22 reported relief. In those 52 consecutive patients, the application of the criteria recommended for patient selection predicted tinnitus relief in 20 of the 22 who reported tinnitus relief. Ultra-high-frequency audiometry is considered essential for the selection of candidates for high-audio-frequency stimulation using either UHF or US for attempting tinnitus relief.

## REFERENCES

1. Goldstein BA, Shulman A, Lenhardt ML, et al. Long-term inhibition of tinnitus by UltraQuiet therapy: Preliminary report. *Int Tinnitus J* 7(2):122–127, 2001.
2. Shulman A, Goldstein BA. Patient Selection: Ultrahigh Frequency Stimulation Attempting Tinnitus Relief. Presented at the conference *Hearing Loss in Children*, Amplifon, Milan, Italy, July 2–3, 2004.
3. Lenhardt ML, Skellett R, Wang P, Clarke AM. Human ultrasonic speech perception. *Science* 253:82–85, 1991.
4. 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, St. Petersburg Beach, FL, February 12, 1999.
5. Shulman A, Strashun AM, Avitable MA, et al. Ultra-high-frequency stimulation and tinnitus control: A positron emission tomography study. *Int Tinnitus J* 10(2):113–125, 2005.
6. Shulman A. Medical audiological evaluation of the tinnitus patients. *Semin Hear* 8(1):7–14, 1987.
7. Shulman A, Tonndorf J, Feldmann H, et al. *Tinnitus Diagnosis/Treatment*. Philadelphia: Lea & Febiger, 1991.
8. Goldstein BA, Lenhardt ML, Shulman A. Tinnitus improvement with ultra-high-frequency vibration therapy. *Int Tinnitus J* 11(1):14–22, 2005.
9. Lenhardt ML. Ultrasonic hearing in humans: Applications for tinnitus treatment. *Int Tinnitus J* 9(2):69–75, 2003.
10. Lenhardt ML, Richards DG, Madsen AG, et al. Measurement of bone conduction levels for high frequencies. *Int Tinnitus J* 8(1):9–12, 2002.