

## METHOD AND APPARATUS FOR TREATMENT OF MONOFREQUENCY TINNITUS UTILIZING SOUND WAVE CANCELLATION TECHNIQUES

### CROSS REFERENCE TO RELATED US APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 60/272,461 filed Mar. 2, 2001, the specification and disclosure of this related application is incorporated herein in its entirety by this reference.

### TECHNICAL FIELD

[0002] Applicant's inventions are related to the treatment of tinnitus patients and more particularly to improved methods and apparatus for treatment of monofrequency tinnitus patients utilizing phase shift cancellation principles.

### BACKGROUND OF THE INVENTION

[0003] Tinnitus is defined as the perception of sound by an individual when no external sound is present, and often takes the form of a hissing, ringing, roaring, chirping or clicking sound which may be intermittent or constant. According to the American Tinnitus Association, tinnitus afflicts more than 50 million Americans and more than 12 million of those suffer so severely from tinnitus that they seek medical attention and many cannot function normally on a day-to-day basis.

[0004] Tinnitus, often referred to as ringing in the ears, is estimated to be present in approximately 50% of the US population over 65 years of age. In general, tinnitus takes many and varied forms which may be related to its underlying cause. Tinnitus may be caused by or related to such diverse factors as trauma, drugs, hearing loss, the normal aging process or other unknown causes.

[0005] In 1825 Dr. Jean-Marie Gaspar Itard published a book in France titled *Maladies of the Ear* in which he stated that tinnitus is a medical problem and that most patients suffering with severe tinnitus did not respond to medical treatments available at that time and most in the medical community believe that is still true today despite major advances in the medical sciences. Itard suggested that external sounds be utilized to interfere with (masking) the tinnitus sound heard by a patient and could be relieved in some instances provided the masking sound bore some relationship to the tinnitus sound heard by the patient.

[0006] As early as 1930 Dr. R. I. Wegel published a paper entitled "A Study of Tinnitus" in which he reported his findings that tinnitus is a pathologic system but that quantitative studies had not been carried forward to a point of being useful in patient diagnosis or effective treatment. The idea of using an external sound generator to mask an obtrusive tinnitus condition dates from 1928 to a work by Drs. Jones and Knudsa although many credit Saltzman and Eisner (1947) with the first successful masking treatment for tinnitus.

[0007] During the 1960s and 1970s additional tinnitus research was conducted at a number of US medical facilities including the Oregon Hearing Research Center in Portland. The Oregon Center began as a laboratory project to study tinnitus induced in animals by drugs. According to Jack Vernon initially through incidental tinnitus patient contacts,

the Oregon Center gradually shifted from an animal lab focus to tinnitus patient clinic to study tinnitus and eventually develop a tinnitus masking device. The Oregon Tinnitus Masker Study resulted in a number of patient specific device recommendations including hearing aids, tinnitus maskers (sound generators) and tinnitus instruments which combine both a hearing aid with a sound generator. Early reports of the Oregon Masker Project reported substantial success in masking treatments for tinnitus patients utilizing all three devices and initially claimed a success rate in the range of 67% for tinnitus patients who accepted the Oregon recommendation of a hearing aid and 81% of tinnitus patients who accepted the recommendation for a tinnitus masker/instrument. A report by Dr. McFadden for the Working Group 89 NRC criticizes these early success reports and states that perhaps they were misleadingly optimistic.

[0008] In reporting on patient studies at the Oregon Tinnitus Clinic, Jack Vernon, director of Oregon Hearing Research Center, stated that in patient tinnitus studies phase and tone relationships are of obvious and critical importance in tone masking of tinnitus. Vernon goes on to state that one cannot repress the idea of canceling tinnitus by a proper phase adjustment of the external tone used in masking. In commenting on Wegel's earlier tinnitus treatment findings that a slight mistuning of a masking external tone produced a beat-like sensation with the tinnitus sound, Vernon reported that in a 100 patient study he was able to detect a slight beat-like sensation in only four instances. Vernon therefore concluded that the beat-like sensation found by Wegel was most probably due to octave confusion resulting in Wegel not using a single pure tone but rather a narrow band of noise. In conclusion, Vernon observed that phase manipulation justifies further patient studies as a masking parameter for tonal tinnitus treatments. Vernon's report on possible phase manipulation for treating tinnitus patients remained unchanged from its original publication in 1991 and as included in the 1997 edition of Shulman's treatise entitled "Tinnitus Diagnosis and Treatment."

[0009] In 'The Origin of Tinnitus,' J. Tonndorf states that little factual information exists about the mode(s) of tinnitus generation. Even today medical approaches to identifying and treating tinnitus continue to be hampered by what little is known about the human auditory system. According to A. Shulman in his 1997 treatise "Tinnitus/Diagnosis/Treatment", attempts to understand and treat or control tinnitus are unfortunately still limited by the lack of suitable models and therefore more flexibility in thinking about and treating tinnitus will be required in order to foster the development of new medical modalities in the diagnosis, treatment and control of tinnitus. Unfortunately today many patients suffering from tinnitus are too often told by their doctors that no effective cure or treatment exists and therefore they will just have to learn to live with their affliction.

[0010] To remedy the current deficiencies in diagnosing and treating tinnitus patients and more particularly monofrequency (single tone) tinnitus, Applicant has developed a new, more efficient phase cancellation treatment process and apparatus that overcomes many of the shortcomings taught by the prior art.

[0011] There is a long-felt need for an effective treatment for monofrequency tinnitus patients to substantially reduce, relieve or eliminate the often substantially debilitating condition of tonal tinnitus.