

AUREX – TELEAUDIOLOGY FOR THE TREATMENT OF TINNITUS

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31st annual conference 'Management of the tinnitus and hyperacusis patient',
University of Iowa, 8-9 August 2024

The Aurex-3® Wearable is a new treatment and management system for chronic tinnitus

Aurex International Corporation (AIC), an ADM Tronics subsidiary, has developed an innovative, easy to use wearable tinnitus therapy device incorporating cloud based interaction via smart phone or tablet for user operation and monitoring through an international network of audiologists.

The underlying principles used in the Aurex-3 have evolved over the last 20 years in using beat harmonics to 'reset' the repetitive memory function associated with tinnitus derived from neurophysiological and/or psychological dysfunction. This is a unique and patented aspect of the Aurex-3 modality.

The beat harmonic excitation is applied via a bone conducting wearable headset to the cochlea and creates a consonant and often relaxing effect. This offers respite to the patient and encourages continued use.

Regular and continued use of the Aurex-3 acts to reverse the 'repetitive memory function' of Tinnitus through neuronal plasticity within the auditory cortex.

The new wearable system is currently undergoing controlled trials in the USA and the UK. This presentation summarises the neurological and psychological aspects of the Aurex modality and describes results obtained in treating tinnitus for rock musicians, veterans, and chemotherapy patients.

Hearing or Listening?

In the late 1950's Berard and Tomatis, French ENT specialists, argued that the ear performs a much greater role than simply allowing us to hear. In particular Tomatis differentiated the concept of listening, absorbing information, from the sensory response of hearing. He observed a close relationship between *how* a person hears and their behaviour, learning abilities, sociability, emotional health and general wellbeing. The success of the subsequently developed Listening Therapy in treating a number of behavioural difficulties attests to the important link between hearing physiology and psychology. In so doing the highly stimulating perceptive response to ordered classical music is used to train to *listen* properly. Thus, the organ of hearing takes on a far greater role and importance.

To understand tinnitus we need to understand how we hear, how we listen and how we perceive sound.

For convenience this may be broken down into three descriptive stages ;

1. Auditory stimulation: sound reception and treatment
2. Auditory transmission: sound conversion and nerve transmission
3. Auditory perception: sound storage and identification

Mechanics of the Ear

Vibrating airwaves (sound) enter the outer ear canal and create a resonating column of air with length about 2.5cm and average diameter 0.8mm. The open end of the ear canal is surrounded by the pinna that provides spatial focussing. The resonance inside the ear canal amplifies the variations of air pressure that make up sound waves, placing a peak pressure directly at the closed, eardrum, end of the canal. For frequencies between approximately 2KHz and 5.5KHz, the sound pressure level at the eardrum is approximately 10 times the pressure of the sound at entry. Air pressure waves set up sympathetic vibrations in the taut component of the eardrum that are then passed on to the solid components of the middle ear. The three bones of the middle ear form a system of levers that are linked together and driven by the eardrum. Working together as a lever and columnar system, the bones may amplify the force of the sound vibrations to up to three times the force of the vibrations at the eardrum. The muscles of the middle ear modify the performance of this lever system as an amplifying unit. They act to protect the ear against excessively loud noises. The vibrations from the middle ear are passed to the oval window covering an opening in the bony case of the cochlea. This oval window is 15 to 30 times smaller than the eardrum producing the critical amplification needed to match the impedance between sound waves in the air and in the cochlear fluid. The incoming vibrations of sound are amplified a further 30 times by this concentration of force. By this combination of mechanisms relatively weak vibrations in air are amplified by more than 800 times so that they can establish pressure waves in the liquid of the inner ear. The pressure waves in the cochlea exert energy along a route that begins at the oval window and ends at the membrane covered round window, where the pressure is dissipated. Complying with the principles of hydraulics, the pressure applied at the

oval window is transmitted to all parts of the cochlea. Hydraulic pressure waves in the cochlea induce a wave like ripple in the basilar membrane which travel from the taut end adjacent to the oval window to the loose end at the other. High frequency sounds vibrate the basilar membrane at the base of the cochlea whilst lower frequency sounds vibrate it at the apex. Frequencies in between have their maximum effects at points like the notes on a piano keyboard. The positions of these crests determine which nerve fibres send signals to the brain.

Neurophysiology of Hearing

Spiralling around within the cochlea is the organ of Corti, a gelatinous mass about 4 cm long that contains a mass of cells almost touching the branch endings of the auditory nerve. From these cells fine 'hairs,' stereocilia, rise in four orderly rows, three outer and one inner. These 23,500 stereocilia are about 2 microns in length and can be likened to transducers. Movements of the inner hairs acts immediately to generate electrical signals which stimulate the auditory nerve, a bundle of about 30,000 individual fibres. Adjacent sensory hairs are linked together by fine filaments called tip links that are like mechanical gates. When there is no sound at that hair cells frequency, the hair stands upright with the tip links 'gate valve' closed. When sound of the appropriate frequency deflects the hair cell, the gate opens and an electrochemical flow is initiated. Movement of the stereocilia leads to gate opening by tiny levers. The tip links are important limiting devices, preventing excessive movements and/or returning to the upright position after deflection. This is likened to spring and switch nanotechnology of molecular dimensions. The flow of charged ions from the hair cell causes glutamate, a neurotransmitter, to be released which stimulates the nerve fibre causing an electrochemical message to rush along the nerve towards the brain.

The tip link 'limit switches' can become damaged by exposure to loud noise such that this flow continues or is disrupted when no sound is present, leading to tinnitus.

Another area of interest follows from the knowledge that over release of Glutamate in other nerve pathways can cause nerve damage by over excitation. Interruption of oxygen supply to the nerve can cause over release of glutamate, leading to tinnitus.

Sound Perception

Emerging from the organ of Corti to form the auditory nerve, the 30000 nerve fibres transmit sound signals to the brain. Nerve fibres lead to different parts of the auditory cortex depending on the frequencies they carry. Descending nerve fibres from the brain carry instructions back to the inner ear to filter out some signals that the brain determines are of no importance or significance and concentrate on others. Sound recognition and response occurs at the auditory cortex that may be likened to the hard disk of a computer. Files of data are maintained as memory functions for each frequency of sound. Long term sound memory functions are an example of neuronal plasticity relying on a rewiring of brain connections. A tinnitus response may thus be imprinted requiring time to redress the balance. Other parts of the brain can

significantly affect the importance that is given to a tinnitus sound. In particular the Limbic system is an important control Centre of the brain comprising the hippocampus involved with incoming sensory information, the hypothalamus which is the emotional and functional barometer/ control unit of the brain and the amygdala which is thought to be more directly involved in emotion. So any history or underlying Psychosis is likely to affect the rate and extent of progress towards rewiring to accommodate the tinnitus sound – habituation.

Aurex-3

The Aurex-3 modality is based on the consideration that hearing is a repetitive memory function in which tinnitus is a result of the brain memory repetitive functions. Based on this the Aurex-3 employs a central vibratory and audio frequency excitation tuned to a broad band surrounding the user's tinnitus. By stimulating the damaged nerve endings in a broad band surrounding the tinnitus sound, the brains repetitive memory attribute will deviate to repeat the sound injected. Eventual inability to reproduce the original tinnitus sound will alleviate the intensity.

The Aurex-3 generates a complex range of frequency spectra from the interactions of three fundamental frequencies (hence 'Aurex-3') together with sideband frequencies. The resulting harmonic frequency spectrum of 200-20,000Hz spans the audible range of 200 to 15,200 Hz (for reference middle C on a piano has a frequency of 256 Hz, human speech tends to be around 300 – 1,000 Hz, sounds above 5,000 Hz are high pitched squeals or screeches). These frequency spectra are applied via a lightweight wearable bone conducting headset and transmitted by bone conduction to the inner ear.

User patterns will vary but typically will involve treatments of 5 minutes duration, 3 times a day for the first two weeks. As benefits are seen the number of treatments may be reduced and the intervals increased.

Experience from using the Aurex-3 is showing some remarkable results and based on subjective evidence amassed from around the world is being regarded as a major new development in the treatment of tinnitus.

The 'Aurex' effect

Central to the Aurex-3 approach is the application of beat harmonics.

Traditionally, dissonance has been widely believed to be the product of "beating": interference between frequency components in the cochlea that has been believed to be more pronounced in dissonant than consonant sounds. However, harmonic frequency relations, a higher-order sound attribute closely related to pitch perception, has also been proposed to account for consonance. Some combinations of musical notes sound pleasing and are termed "consonant," but others sound unpleasant and are termed "dissonant."

Contemporary thinking on consonance is instead rooted in acoustics, beginning with the fact that musical instrument and voice sounds are composed of multiple discrete

frequencies. These frequencies are termed “harmonics” because they are typically integer multiples of the fundamental frequency of the sound. Harmonics are combined in a single waveform when traveling in the air but are partly segregated by the cochlea, because different auditory nerve fibers respond to different frequencies (*Plomp, R. The ear as a frequency analyzer, J Acoustic Society America, 36, 1964*).

When several notes are combined, the resulting sound waveform that enters the ear contains all the individual frequencies of each note. Auditory scientists have long noted that aspects of the pattern of component frequencies differ between consonant and dissonant chords. Prevailing theories ascribe consonance to the fact that dissonant chords contain frequency components that are too closely spaced to be resolved by the cochlea. Two such components shift in and out of phase over time, producing an interaction that oscillates between constructive and destructive interference. The amplitude of the combined physical waveform thus alternately waxes and wanes. If the components are close enough to excite the same set of auditory fibers, amplitude modulations are directly observable in the response of the auditory nerve. These amplitude modulations are called “beats,” and result in an unpleasant sensation known as “roughness,” analogous to the tactile roughness felt when touching a corrugated surface [in practice, the perception of roughness is dependent on the depth and rate of amplitude modulation, as well as the center frequency of the tones involved. Theories of dissonance based on beating have been dominant in the last century and are now a regular presence in textbooks (*Deutsch, D., The psychology of music, Academic, San Diego, 2009*).

However, a second acoustic property also differentiates consonance and dissonance: the component frequencies of the notes of consonant chords combine to produce an aggregate spectrum that is typically harmonic, resembling the spectrum of a single sound with a lower pitch. In contrast, dissonant chords produce an inharmonic spectrum. Such observations led to a series of analyses and models of consonance based on harmonicity (*Ebeling, M. Neuronal periodicity detection as a basis for the perception of consonance, J Acoustic Society America, 12, 2008*) Although beating-based theories are widely accepted as the standard account of consonance, harmonicity has remained a plausible alternative. Mc Dermott et al (*Mc Dermott, JH, et al, Individual differences reveal the basis of consonance, Curr Biol, 20, 2010*) argues that harmonicity is more closely related to consonance than is beating.

This disassociation of harmonicity from beating in the Aurex-3 and its unique matching to a person’s Tinnitus sound presents a unique and differentiated model and modality for Tinnitus treatment.

Operating Principles

Almost all sounds are complex in nature containing several component parts.

For example, if a single note such as the ‘A’ immediately above middle ‘C’ on a piano is played, then the correctly tuned piano string will vibrate at 440Hz. If the sound is analyzed, it will be found to contain harmonics as integer multiples of 440Hz, 2,3,4

times etc. The exact composition of this harmonic series in terms of the amplitude of each harmonic, and the extent in number of harmonics determines the characteristic of the sound, in this case a piano. If a violin were played at the same pitch of 440hz, then the harmonic series of its sound will be correspondingly different.

- The Cochlea is capable of 'decoding and separating' this harmonic series and transmitting to the brain an analog of this harmonic series through the auditory nerve. The auditory cortex of the brain then, from the process of learning recognition, can reconstruct this sound and recognize it as in this case, a piano or violin.
- Tinnitus is due to the artificial stimulation of particular nerve cells in the parts of the brain responsible for processing sounds, each nerve cell having an assigned frequency. Whilst the cause of this may not be known, the patient does know the sonic nature of these sounds, for he hears these sounds.
- In the Aurex-3 a complex signal is derived from a high frequency sonic tone modulated by a low frequency sonic tone. This signal actuates a transducer to produce vibrations whose repetition rates correspond to the frequencies of the complex signal which frequencies are like those which make up the tinnitus sounds.

In general terms, this signal will be created by the intermodulation of 2 audio signals each having a complex nature to create a wide spectrum of beat harmonics.

Each audio signal is frequency modulated by a third modulation frequency to generate further sideband pairs of frequencies.

The signal resulting from the above processes is then applied to a low pass filter of adjustable cut off frequency so that the degree of harmonic and sideband pair may be controlled.

Tele audiology – The Aurex app

The Aurex platform uses synchronous tele-audiology whereby a patient can be assessed and device settings chosen in real-time as if the patient is sitting in front of their audiologist. Remote testing where a patient is in a sound booth while the audiologist sits outside the booth is virtually the same as testing the patient over the internet.

The Aurex app provides an easy way for patients to interact with their audiologist via their smartphone. Following a secure sign up/login process, patients can review their treatment plans with their audiologist. The audiologist can match the patient's tinnitus to optimize settings and monitor usage and progress towards improvement targets with the patient. Treatment plans with reminders are used to motivate the user and support compliance with regular news updates informing of the Aurex community experiences together with new research and information on tinnitus.

User Experience

There are many causes of tinnitus.

In most cases, tinnitus is a sensorineural reaction in the brain to damage in the auditory system. While tinnitus is often associated with hearing loss, there are many different health disorders that can generate tinnitus as a symptom.

Noise-induced hearing loss

Exposure to loud noise, either a single traumatic experience or over time, can damage the auditory system and result in hearing loss and sometimes tinnitus as well.

Nick Brown is a former guitarist with post punk band The Membranes;

“It is essential for the person’s well-being to accept that Tinnitus is here to stay. Learning how to accept it is difficult and will take a long time. The Aurex can help both with this process of learning to habituate and beyond: to ignore the T to the point that the noise is less distressing thus allowing the individual to continue with their lives as normally as possible whilst being mindful of their condition.”

Traumatic Brain Injury (TBI)

Traumatic brain injury, caused by concussive shock, can damage the brain’s auditory processing areas and generate tinnitus symptoms. TBI is one of the major catalysts for tinnitus in military and veteran populations.

Dr Hilary Wynn-Williams MD developed tinnitus after serious head injury from a RTA;

“I have had Tinnitus for 29 years. Both tinnitus and deafness made my work as a GP impossible. I now compose summaries of patients’ medical histories from the confusion of their medical notes and letters. This is very useful to doctors, essential for training and satisfying for me.

This state of mind has been aided by the treatment of my tinnitus by Aurex-3.

The tinnitus level is graded and after three months there has been a reduction from 8 to 2 and the reduction has been maintained.

Since using Aurex-3 my sleep, and therefore general well- being, are much better and I no longer wake up in the night. This improvement has been gradually progressive.”

Ototoxic Drugs

Tinnitus is a potential side effect of many prescription medications. However, in most cases and for most drugs, tinnitus is an acute, short-lived side effect. However, there are some ototoxic drugs that cause permanent tinnitus symptoms. Particular interest is focused on Platinum Based Chemotherapy (PBCT).

Although the aim of cancer treatment is survival, ototoxicity encountered after PBCT, which is often permanent and not preventable, needs careful consideration for those living with and beyond cancer.

Dr Joe Piacentile is a MD and lawyer who has been living with tinnitus for the last 8 years following ototoxicity associated with a number of treatments for head and neck conditions including chemotherapy:

“After using the Aurex for 2 weeks I had the first quiet day for 8 years. With continued use I am now getting several days of respite and overall reduced levels of tinnitus in between. I am fascinated to learn more about the Aurex modality and have established user trials in the US as lead investigator to enable more people to benefit from this therapy.”

Future Developments

The Aurex-3 technology is patented as a continuation from the original design as ‘An electronic stimulation system for treating tinnitus disorders’, Di Mino et al US patent # 6,210, 321 B1.

Pre- clinical trials are underway in USA and UK with the availability of an FDA cleared consumer variant planned for early 2025.

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