

Safety of the HyperSound® Audio System in subjects with normal hearing

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Abstract

The objective of the study was to assess the safety of the HyperSound® Audio System (HSS), a novel audio system using ultrasound technology, in normal hearing subjects under normal use conditions; we considered pre-exposure and post-exposure test design. We investigated primary and secondary outcome measures: i) temporary threshold shift (TTS), defined as >10 dB shift in pure tone air conduction thresholds and/or a decrement in distortion product otoacoustic emissions (DPOAEs) >10 dB at two or more frequencies; ii) presence of new-onset otologic symptoms after exposure. Twenty adult subjects with normal hearing underwent a pre-exposure assessment (pure tone air conduction audiometry, tympanometry, DPOAEs and otologic symptoms questionnaire) followed by exposure to a 2-h movie with sound delivered through the HSS emitter followed by a post-exposure assessment. No TTS or new-onset otological symptoms were identified. HSS demonstrates excellent safety in normal hearing subjects under normal use conditions.

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Introduction

The HyperSound® Audio System (HSS) is an audio system using novel technology designed to create sound from ultrasound in the air. It is found to significantly increase intelligibility for those with hearing loss¹ and has received a Food and Drug Administration (FDA) clearance for use: *...as a group hearing aid used to communicate simultaneously with one or more listeners with or without hearing loss and with or without the use of hearing aids in order to improve clarity and comprehension of sounds...*

In clinical studies, HSS demonstrates highly significant improvement in unaided speech recognition over conventional speakers at 70 dB SPL, including in background noise, in those with mild to severe hearing loss.²

HSS electronically converts audible information onto ultrasonic waves transmitted at frequencies well above human hearing. Audio is carried along a beam of silent ultrasound energy and demodulated in the air, reproducing sound such that it can be heard only by those in the targeted area. Unlike a conventional speaker, sound is not created omni-directionally at the speaker (emitter) surface, but is created within a directional air column or beam. Sound is heard only if a listener's head is within the beam or the beam hits a reflective surface whereupon sound is scattered omni-directionally at the point of reflection. This sound, which is created in the air, can be directed to nearly any desired point in the listening environment. Since the sound is created along a beam, the intensity of the amplified sound is maintained over longer distances compared to the transmission of sound through a conventional audio speaker. The transmission of sound in a narrow beam has several purported advantages to the listener, including the ability to maintain a more favorable signal-to-noise ratio, which results in improved speech intelligibility.¹

Parametric production of audio from ultrasound was first proposed in 1963 by Peter Westervelt who was the first to theorize that highly directional receivers and transmitters may be constructed utilizing the nonlinearity of the equations of fluid motion, work that has been further developed by several others.³⁻⁵ This effect was observed experimentally in water in 1972⁶ and finally in air by Bennett in 1974.⁷ The effort to transform this research into a consumer product needed both an increase in sound volume and reduction in distortion. Piezoelectric crystals⁸ and films⁹⁻¹¹ were shown to produce airborne ultrasound with sufficient efficiency and volume to be useful for parametric audio. A reduction in distortion requires high-speed digital signal processing, which, until recently, was not available.

Parametric audio systems by various manufacturers have been in commerce since the mid 1990's. The authors are unaware of any reported health issues from such devices and research indicates that airborne ultrasound has little effect on general health.¹² Ultrasound with frequencies close to the range of human hearing (<80 kHz) can produce subharmonic tones at 1/2 or 1/4 frequency which can be perceived and it is high levels of audible noise from these subharmonics which contributes to reports of headache and nausea.¹² As this is a

nonlinear phenomenon, each order of nonlinearity (halving of frequency) will be greatly reduced in magnitude.¹³ The ultrasonic output from the HSS emitters studied in this manuscript is 96 kHz+. Unlike low-frequency ultrasound (<80 kHz), the 3rd-order (1/4 frequency) subharmonic is outside the range of human hearing. The 4th-order (1/8 frequency) subharmonic lies within the range of human hearing, but is inaudible due to the higher-order of nonlinearity and subsequent greatly reduced intensity level.

From an energy perspective, HyperSound® is below all exposure limits set forth by the FDA for allowable internal ultrasonic intensity. The body reflects 99.9% of airborne ultrasonic energy due to the acoustic impedance mismatch of air to tissue.¹⁴ At 2 m the maximum energy density of ultrasound produced by HyperSound® is 2.9 mW/cm² and of this, only 0.0029 mW/cm² at maximum enters the body due to reflection by the skin. The FDA standard for internal ultrasound is 720 mW/cm² for fetal, cardiac, and vascular imaging and 50 mW/cm² for ophthalmic imaging.¹⁵ This represents a safety margin of greater than 1/17,000 from the FDA standard for non-invasive medical applications of ultrasound.

Exposure to loud sound can cause elevated hearing thresholds, or threshold shifts. A temporary threshold shift (TTS) occurs when hearing thresholds shift and then return to normal or baseline within 16 to 48 h. Hearing loss caused by noise exposure is determined by the intensity of the noise and the duration of exposure to the noise. With repeated exposure to noise that cause TTSs, threshold shifts may become chronic or even permanent.¹⁶

Materials and Methods

Participants

Participants included 20 subjects aged 18 years and older with normal hearing. Patients with a history of otologic disease or surgery were excluded.

Outcome measures

The primary outcome was the presence of a TTS, defined as a 10 dB or greater shift in pure tone air conduction threshold at two or more frequencies and/or a decrement in post-exposure distortion product otoacoustic emissions (DPOAEs) of greater than 10 dB at any two of six frequencies between 1500-6000 Hz. A decrement of greater than 10 dB in post-exposure otoacoustic emissions was chosen in order to differentiate clinically significant change from expected test/re-test variability.¹⁷⁻²⁰ The secondary outcome measure was defined as the presence of new otologic symptoms after exposure to the HSS including aural fullness, aural pressure, tinnitus, otalgia, dizziness, vertigo, or headache.

Procedures

All data were collected during one visit to the clinic by a certified audiologist trained in research data collection. The same audiologist performed pre and post-exposure testing for all subjects. The study was approved by a central Institutional Review Board (IRB) and is registered on Clinicaltrials.gov. All research was conducted under good clinical

practice) guidelines. No animals were used for this study. After signing an informed consent form, baseline hearing level was determined by testing pure tone air conduction thresholds at 250-8000 Hz (Interacoustics Equinox PC-based Audiometer). In addition, tympanometry was conducted to establish normal middle ear function at baseline (Interacoustics Titan) and DPOAEs were conducted at 6 individual frequencies from 1500-6000 Hz to establish normal cochlear function (Maico ERO SCAN Pro). Demographic data and hearing loss history was recorded. A verbal questionnaire was administered regarding otologic history, hearing loss history, and presence of current ear/otologic symptoms including aural fullness, aural pressure, tinnitus, otalgia, dizziness, vertigo, headache, or recent loud noise exposure.

Participants were then seated in a study room where they were seated 2 m and 0° azimuth from each of two stereo sound sources (HSS emitters) one directed at each ear. Participants were continuously exposed to sound delivered through the HSS emitters for 113 min while watching a movie (*Edge of tomorrow*). The sound level delivered through the HSS emitters at the participant location was set to 80 dBA using a multitone pattern of 1, 1.5, 2, and 4 kHz, all set to equal level. The test conditions were exactly the same for all participants.

After the HSS exposure (upon completion of the movie), subjects were immediately brought to the sound booth for post-exposure testing which entailed the same pre-exposure test battery described above with the exception of tympanometry.

The pre-exposure thresholds and post-exposure thresholds at all tested audiometric frequencies as well as pure tone average (PTA) thresholds were compared using a paired, 2-tailed t-test at a significance level of P<0.05.

Results

Baseline characteristics for all 20 participants are presented in Table 1. There were 8 males and 12 females with a mean age of 29 years (range 21-53 years). All subjects had normal hearing, normal middle ear function on tympanometry, with present DPOAEs from 1500-6000 Hz on pre-exposure testing.

Following exposure to a 113-min movie with audio played through the HSS emitter, Post-Exposure testing showed no significant changes in pure tone hearing thresholds or DPOAE thresholds. No statistically

Table 1. Participant baseline (pre-exposure) characteristics.

Characteristic	N=20
Male gender, n (%)	8 (40%)
Female gender, n (%)	12 (60%)
Age (years), mean±SD	29±7 (range: 21-53)
PTA (dB), mean±SD	
Right ear	5.9±4.5
Left ear	6.1±4.2

SD, standard deviation; PTA, pure tone average.

Table 2. Pure tone average thresholds: pre-exposure vs post-exposure.

Condition PTA*	Pre-exposure			Post-exposure			P-value ^o
	Mean±SD	Median	Range	Mean±SD	Median	Range	
Right ear (dB)	5.9±4.5	5	-5 dB to 12.5 dB	5.8±4.2	5	-3.75 dB to 12.5 dB	0.85
Left ear (dB)	6.1±4.2	6.25	-3.75 to 13.75	6.4±4	6.9	-2.5 dB to 13.75 dB	0.33

PTA, pure tone average; SD, standard deviation. *All thresholds in decibels (dB); ^oP-values were obtained from the paired, 2-tailed t-test.

significant changes were detected between the pre-exposure thresholds and post-exposure thresholds at any audiometric frequency tested as well as PTA thresholds (Table 2). None of the participants reported any new onset otological symptoms (aural fullness, aural pressure, tinnitus, otalgia, dizziness, vertigo, headache) following exposure. One participant reported non-bothersome bilateral tinnitus of eight years duration on pre-exposure assessment. This remained unchanged on post-exposure assessment. One participant reported bilateral aural fullness attributed to recent onset of allergies on pre-exposure assessment. This participant reported no change in aural fullness on post-exposure assessment.

Discussion

HSS system models employing the same directional audio technology as tested in this study have been sold for general, non-clinical use since 2001, primarily for retail digital advertising applications. Since the system is an electrical emitter of ultrasonic vibrations it is regulated under the Radiation Control for Health and Safety Act of 1968 (title 21, code of Federal Regulations, Subchapter J). In 2014, HSS received FDA clearance as a medical device and is indicated for use as a group hearing aid for one or more listeners with or without hearing loss and with or without the use of hearing aids in order to improve clarity and comprehension of sounds generated from sources such as a microphone, CD/DVD player, TV, stereo system, or other sound generation systems.

Clinical studies of HSS in subjects with mild to severe hearing loss demonstrate that participants experienced significantly improved speech intelligibility scores when listening to sound through the HSS compared to a conventional speaker at 70 dB SPL in a controlled, laboratory environment.² One reason that participants experienced greater speech intelligibility with the HSS may be due to the precise targeting of sound within a narrow beam. Unlike a conventional audio speaker, which disperses sound omni-directionally from the speaker surface, the HSS creates sound along and within a tight, directional air column. The precision targeting of the HSS significantly minimizes the effects of ambient noise and reverberation, so the sound beam maintains a clear, high-fidelity audible signal over a relatively long distance. The HSS produces audio by using the natural nonlinear properties of air, thus producing sound *in the air* rather than on the surface of a speaker. This allows the listener to receive the transmitted sound before reverberation or ambient noise interferes with the acoustic signal. Another explanation relates to the frequency response of the HSS compared to conventional speakers. It is possible that the HSS more effectively transmits a broader bandwidth signal with more high frequency information relative to the conventional speaker. Given the positive effects of additional high frequency energy on speech intelligibility,²¹ it is possible the HSS is able to provide greater audibility of high frequency sounds, which contribute to improved speech understanding. Both of these explanations require further, systematic investigation. HSS may have significant implications for improvements in quality of life of patients with a range of hearing losses.

To date, there have been no subjective or objective adverse effects reported from the HSS system, including in clinical trials demonstrating superior sound clarity when listening to sound through the HSS compared to a conventional audio speaker. The current study adds further objective and subjective safety data in twenty normal hearing subjects under normal use conditions. The duration of exposure chosen for this study (113 min movie) was felt to be a typical use scenario for the use of HSS. Future studies can be designed to assess longer duration of exposure. Additionally, future studies will also investigate the unique properties of ultrasonically transmitted sound for a variety of

hearing losses with and without amplification.

Given the results of this study, HSS appears to be an extremely safe, novel technology that uses the natural, nonlinear properties of air to produce a narrow beam of sound. In comparison to other medical uses of ultrasound such as diagnostic ultrasonography for vascular, fetal, cardiac, or ophthalmic indications, the peak intensity of ultrasound energy able to couple into human tissue from HSS is 17,000 times lower than the strictest allowed intensity for ophthalmic ultrasound and 180,000 times lower than the maximum allowed intensity for fetal ultrasound (Internal Data, Turtle Beach Corp.).¹³

Conclusions

The HyperSound® Audio System demonstrates excellent safety in normal hearing subjects under normal use conditions.

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