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## Scientists Develop A Way To Induce Temporary Hearing Loss In Human Subjects

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*GAINESVILLE, FL*—Hearing scientists have learned much of value about hearing, hearing loss, and its causes and treatments by conducting research experiments on laboratory animals. However, no matter how promising a procedure or drug seems to be in animal studies, at some point before a new treatment is made available to the public, researchers must find out if what worked on mice or chinchillas is also effective for humans.

Designing human clinical trials is complicated by issues of safety and ethics that do not arise with research subjects of other species. For example, prototype drugs have been developed that prevent a temporary noise-induced hearing loss in lab animals from becoming permanent. But it has been difficult for researchers to determine if such drugs will do the same for humans. That is largely because they lacked an effective method of causing a temporary, reversible hearing threshold shift in human subjects that they could be certain would not become a permanent hearing loss.

Recently, however, a group of scientists reported in *Ear and Hearing* that they had developed a real-world digital music exposure that reliably induces temporary threshold shift (TTS) in normal-hearing human subjects.

The lead investigator, Colleen Le Prell, PhD, an associate professor in the Department of Speech, Language, and Hearing Sciences at the University of Florida, and her colleagues enlisted 33 subjects for the studies, which measured the effects of digital music player use on hearing. Subjects selected either rock or pop music, which was presented to them for four hours on a digital music player via headphones. The music was presented at three different levels: 93 to 95 dBA to 10 subjects, 98 to 100 dBA to 11 subjects, and 100 to 102 dBA to 12 subjects.

Audiograms and distortion product otoacoustic emissions (DPOAEs) were measured before the music exposure and then four times during the first 3-1/4 hours after exposure and again one day and one week after the test. Fifteen minutes after the music stopped, those who listened to the highest music levels had lost a small amount of hearing—six dB, on average. Their hearing returned to normal within three hours.

In their conclusion, Le Prell et al. state, "These data provide insight into the variability of TTS induced by music-player use in a healthy, normal-hearing, young adult population, with music playlist, level, and duration carefully controlled. These data confirm the likelihood of temporary changes in auditory function after digital music-player use.

"Such data are essential for the development of a human clinical trial protocol that provides a highly powered design for evaluating novel therapeutics in human clinical trials.

"Care must be taken to fully inform potential subjects in future TTS studies, including protective agent evaluations, that some noise exposures have resulted in neural degeneration in animal

models, even when both audiometric thresholds and DPOAE levels returned to pre-exposure values."

Le Prell's group plan to use this testing model in two clinical trials of therapeutics designed to determine if noise-induced hearing loss can be prevented in humans.

Interviewed for the *University of Florida News*, Le Prell said, "We really want to find out what's going to work and we want to make it possible for strategies that do work to get in the hands of the people who need them."

In the same article, Jianxin Bao, an associate professor at Washington University School of Medicine in St. Louis and an expert on hearing, said, "Dr. Le Prell started with a unique idea to create a reversible noise-induced hearing loss and has established solid groundwork for this new model in the use of clinical drug testing."

Dr. Bao, who was not involved in the study, added, "As for every new model, several unknown factors exist for this elegant experiment model, which requires further detailed studies."