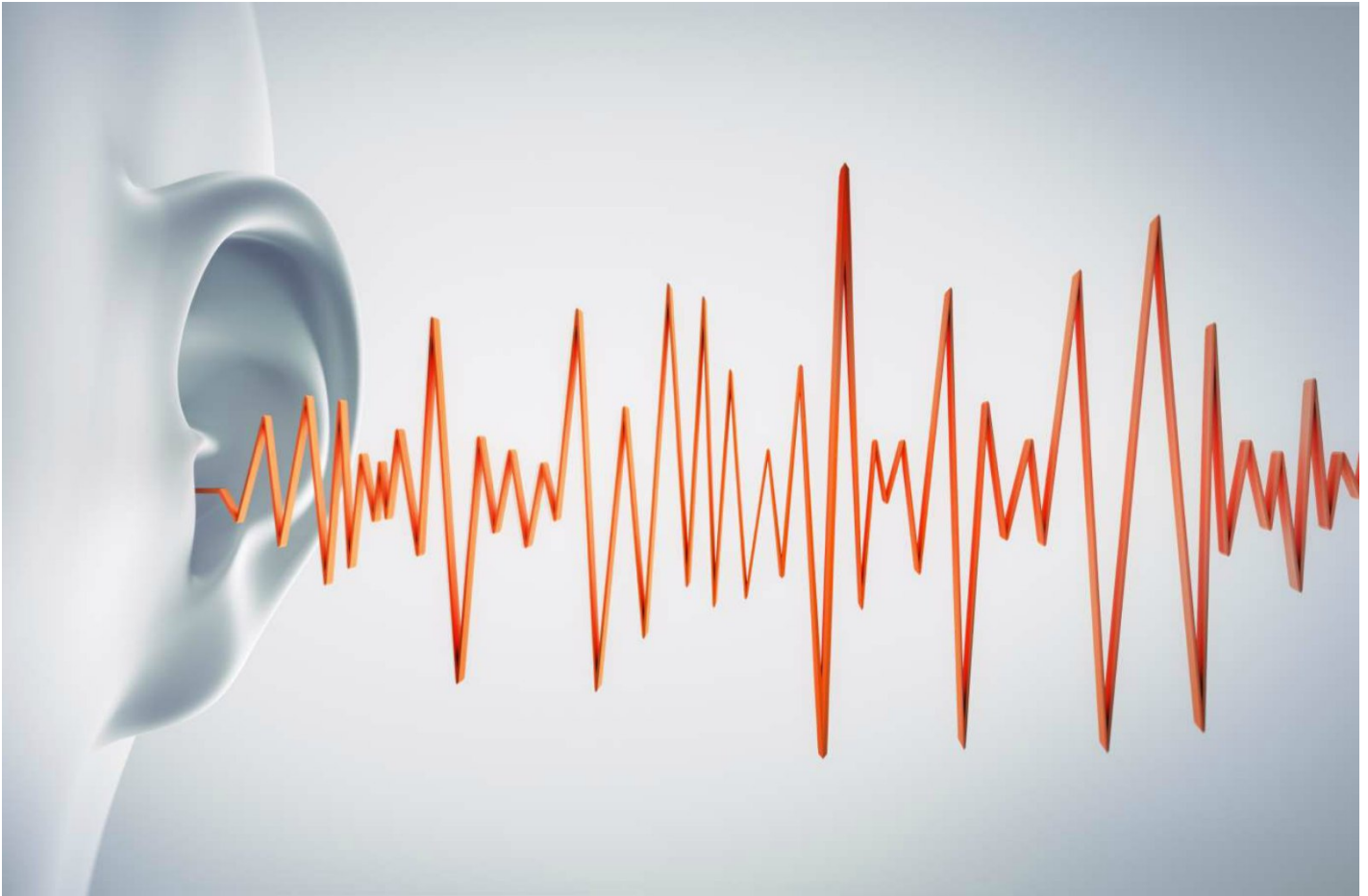


Relief From Ringing In The Ears Gives Tinnitus Sufferers "Their Lives Back"

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Imagine that all day every day you hear a ringing in your ears. Sometimes it is a moderate buzzing and you can function through it. Other times, it is so loud that the only good option is to pray for sleep.

That's what it feels like to have tinnitus, which is defined as the perception of sound when there's no external noise causing that sound. It's a condition that affects about 50 million Americans and is particularly common in the military since it's often caused by loud noises. The constant ringing impacts people's ability to work, their mood and interactions with their families.

So when a University of California, Irvine researcher discovered — somewhat by accident — a method to quiet that ringing, it was a true eureka moment.

"For both the patient and us, that was a wonderful moment," says Fan-Gang Zeng, Ph.D., director of the school's Center for Hearing Research.

What Zeng and his students discovered was that low frequency sounds delivered into the patient's ear temporarily blocked his tinnitus. That knowledge has been refined into an iPod-like device that audiologists give patients to take home and use when they need it. The device, called the Serenade, was formally launched in March to great acclaim from the tinnitus community and their doctors, according to Bill Perry, CEO of SoundCure, the company developing Serenade.

"People's lives are changing," Perry says of patients using the device. He recalls that one woman he talked to recently told him, "I've got my life back. This has been a miracle for me."

An Accidental Discovery

The miracle started with a desperate phone call.

An ear, nose and throat doctor at Stanford University had a patient with devastating tinnitus. The doctor had tried every therapy he could think of, including a cochlear implant, which is normally used to help the deaf. Some research had shown that it could help tinnitus, as well. The patient, a man who worked in the music industry, was often debilitated by the tinnitus attacks and had lost his job and was struggling with depression. He was ready to try anything that might work.

When the implant failed to stop the ringing, that doctor called Zeng, who is recognized as a cochlear implant expert. At the time, Zeng says, he knew almost nothing about tinnitus. But he was up for the challenge.

Zeng says he told the patient, "I don't have any experience, but if you don't give up, I won't give up either."

In his lab, he started experimenting with delivering high-frequency sounds into the implant, which was the prevailing opinion on how cochlear implants could be used to treat tinnitus.

Month after month the man came to the lab, and none of the sounds worked. One morning, after six months, Zeng decided to try something different and used a low-frequency sound instead.

"After a minute and a half, all of a sudden the high-pitched tinnitus went away," Zeng remembers. "He [the patient] said, 'You guys get out of here. I just want to enjoy a moment when I'm not bothered by tinnitus.' And he locked himself in that room to get some relief."

Replicating that Success and Moving to Commercialize

Zeng then needed to find out if he could have the same success with other tinnitus sufferers who did not have cochlear implants. He got funding from the American Tinnitus Association to do a two-year study. The \$180,000 grant was crucial, he believes, since the National Institutes of Health would not have funded his research because Zeng has no track record with tinnitus.

When he put out a call for volunteers, he got responses from about 1,000 people who were eager for relief. He ended up seeing about 100 of them, 10 of whom were military veterans. According to the American Tinnitus Association, the condition is the No. 1 service-connected disability for military personnel.

Zeng got a full data set from 20 of his volunteers. Of those, a third had their tinnitus vanish or nearly vanish while using the device, a third got moderate relief and a third saw no improvement.

Zeng and other researchers still don't fully understand why the sounds, which the company calls S-Tones, help so many people. They appear to be stimulating the brain in a way that cancels out the patient's perception of the

constant ringing.

“This is a sound we know the brain likes,” he says.

At that point, Zeng knew he had a commercially viable product that could bring relief to millions of people. So he contacted his university’s Office of Technology Alliances.

The office believed that the technology would be attractive to investors, explains Ronnie Hanecak, UC Irvine’s assistant vice chancellor for research and technology alliances.

“We felt it had potential because Professor Zeng studies actual patients in his testing lab,” she says. “He’s not working with animals or hypothesizing things.”

The office included the technology in a portfolio of available innovations for a private equity fund, Allied Minds, to review. Allied Minds liked it and took a year-long option to further explore the technology. In 2010, Allied Minds licensed it.

Because Allied Minds had previously licensed other technologies from the University of California for commercial development, the office felt confident that the process would go smoothly.

“This is going to be much more straightforward,” Hanecak says she thought at the time. “They’re not newbies.”

She was correct. The company took the technology and ran with it, bringing it to market in what is considered lightening speed for a medical device.

Getting the Technology to Tinnitus Sufferers

Allied Minds created SoundCure to develop the device and hired Perry to lead the company.

SoundCure, based in San Jose, Calif., developed the hardware and software for the Serenade. The S-Tones, which are delivered through earphones connected to an iPhone-sized device, are customized to each patient. Patients wear the earphones whenever they need relief. They can also use the device as part of an ongoing sound therapy program to achieve longer term relief, Perry explains.

Serenade got its Food and Drug Administration clearance in August 2011. The next month it started a pilot program in three markets, working with doctors who sold it to their patients. The process works much like a hearing aid, where the doctor fits it and provides follow-up care for the patient. Doctors decide the price for the patient and generally charge between \$2,000 and \$2,500 for the Serenade, depending on what services they bundle into the package.

SoundCure continues to work closely with the clinicians, with ongoing training so they know how to best help their patients.

According to Perry, the doctors they’ve worked with are “over the moon” to have this tinnitus solution to provide their patients. Patients are ecstatic as well.

“*One woman, he recalls, “who after years of suffering and not being able to fall asleep — struggling every night for hours to fall asleep, being irritable, stressed, worried — is able to fall asleep.” Bedtime is no longer dreaded.*”

Another favorite comment was from the wife of a patient.

“His wife said, ‘He’s laughing again. He’s relaxed. He’s sleeping,’” Perry remembers. “She said, ‘I feel like this has given me my husband back.’ It gives me chills to think about it.”

The company formally launched the device at the end of March at the annual meeting of the American Academy of Audiology. Perry says the reception was amazing.

“It was beyond our best expectations,” he says. “We had hundreds of audiologists come up and ask for information. ... In the 20 years I’ve been involved in medical device launches, this was the most excitement, the most momentum.

“It really shows how much these patients have been suffering.”

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