SMALL TECH IMPLANTS ARE RESTORING, IMPROVING SOUND FOR HEARING IMPAIRED

Oct 24, 2001 -

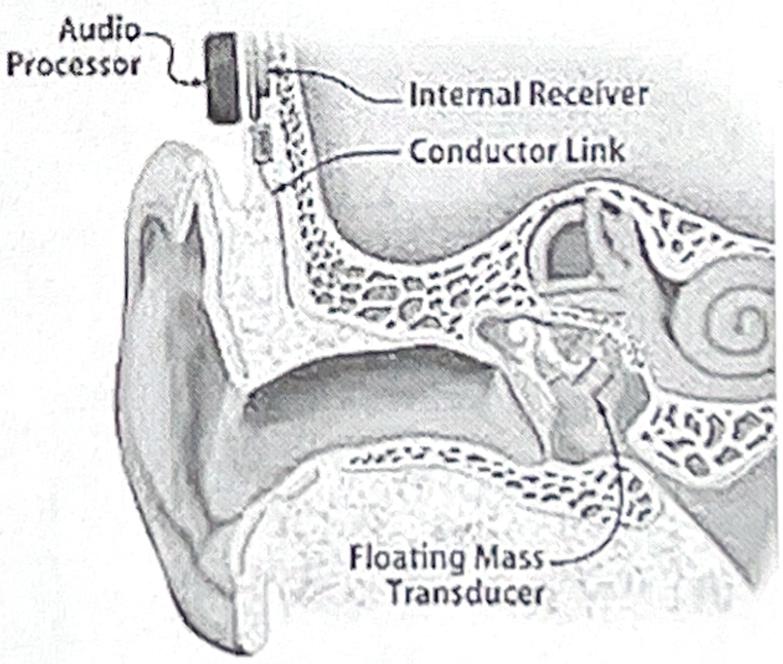
By Rosemary Clandos
Small Times Correspondent

October 24, 2001 – A gold wire, thinner than a human hair, runs from a quarter-sized microphone and audio processor behind Geoffrey Ball's ear, through a tiny hole and into his middle ear. There, an implanted transducer connected to one of the delicate bones in Ball's inner ear takes over for nature and vibrates the bone to create sound.

Ball, who had lost 90 percent of his hearing by age 10, developed the first semi-implantable hearing device to be approved by the U.S. Food and Drug Administration. A clinical test presented to the **American Academy of Otolaryngology** last month concluded that Ball's device, the Vibrant Soundbridge, is safe for long-term use by people with moderate to severe sensorineural hearing loss. The Vibrant Soundbridge has been used in Europe since 1996.

Two other implants hold similar promise when they reach the U.S. market, researchers say.

Otologics LLC, based in Boulder, Colo., has developed a semi-implantable device similar to the Vibrant Soundbridge. A tiny hole is drilled into the incus and a transducer is inserted. The system contains microscale bellows that allow the transducer to vibrate and stimulate the bones in the middle ear. As a result, fluid in the inner ear vibrates and stimulates the auditory nerve.



An implanted transducer is connected to one of the delicate bones in the inner ear and vibrates the bone to create sound. *Courtesy Symphonix*

Zach Cybulski, vice president of technology and operations, said that the device has been released in Europe and he hopes to receive FDA approval by the end of 2002.

For patients who have profound hearing loss and are not candidates for a middle ear implants, a second generation, low-power cochlear implant is being developed by a team at the **University of Michigan**. They are incorporating an array of 128 electrodes that will be inserted into the inner ear (or cochlea) to electrically simulate the auditory nerve. Currently, cochlear implants only use between eight and 22 electrodes.

External hearing aids can cause feedback, voice distortion and wax buildup in auditory canal.

"If you don't like a hearing aid, you can't do anything except have people talk louder," said Ball, chief biomedical engineer and founder of **Symphonix**, based in San Jose, Calif.

Results from the recent clinical study have shown that about 90 percent of the patients

who were implanted with the Vibrant Soundbridge for up to six years continued to report satisfaction with sound, minimal background noise and wearability, according to Symphonix.

Symphonix uses digital processing technology developed by **Siemens Audiologische Technik GmbH** in Germany. Since 1999, the companies have had a distribution partnership for most markets in Europe. Recently, **Siemens Hearing Instruments Inc.**, a world leader for hearing aids, signed a deal to collaborate with Symphonix on outreach programs to audiologists in the U.S.

About 28 million Americans have sensorineural hearing loss. Sounds enter the middle ear but nerve impulses do not reach the brain. This condition is caused by disease, loud sounds, aging and as a side effect of some medicines.

To stimulate the auditory nerve, the Vibrant Soundbridge uses mechanical energy. A surgeon makes a small hole behind the ear and creates a tunnel. A floating mass transducer that is approximately half the size of a grain of rice, is pressure-fitted onto the incus, one of the three tiny bones in the middle ear. The transducer causes the bones to vibrate and move the fluid in the inner ear, thereby stimulating the auditory nerve.

"You only need 10 microns of motions in the human ear – it doesn't take a lot of motion to get a lot of sound," said Ball. Patients can regulate the sound of the device so that it's not too loud. The external piece can be removed for sleeping.

The device cannot be implanted in patients who do not have bones in the middle ear or who have conductive hearing loss, a condition where sound does not reach the middle ear or where there is a mechanical defect in the middle ear. In the future, Ball said, the technology may be adapted for conductive hearing loss.

Technology in the lab today mean music to the ears of people with hearing impairments, said **Kensall Wise**, professor of electrical engineering and computer science at the University of Michigan. Michigan's implant array of 128 electrodes will improve sound perception, Wise said.

"Present cochlear implants work reasonably well in speech, but they don't work well on music and in the case of languages that encode words in pitch and inflections. They sound flat and you don't hear the pitch or tonality of the speech as much as you hear the edges of the sound."

In Chinese, two words can have the same general sound, but the pitch or tone can change the meaning. Music is not very enjoyable with cochlear implants, he said, because they can't produce a very broad range of pitch or frequencies.

Wise has received funding from the **National Science Foundation**, **U.S. Defense Advanced Research Projects Agency** (DARPA) and several companies that already have first-generation cochlear implant devices such as **Advanced Bionics** in Los Angeles and **Cochlear Corp.** in Australia.

"They can take the pieces of what we do and benefit their products," Wise said. "That's how we can get these advances into the products as quickly as possible."

Wise said he expects to begin animal tests in two years. Within five to seven years, a product may be on the market.

Officials at Symphonix said their greatest obstacle has been educating patients and medical professionals about the new technology. If any of the primary physicians, audiologists, surgeons and ear, nose and throat specialists do not recommend the device or consider it experimental for their patients, then fewer implants will be sold.

In August, the company expressed concerned that its stock could be delisted by Nasdaq if it fell below $1 per share. However, since Sept. 11, all delisting issues have been temporarily set aside.

Symphonix may be facing some price issues with insurance companies. The cost of a traditional behind-the-ear hearing aid is about $3,500. The Vibrant Soundbridge can cost about $15,000, including surgery and follow-up care. Some providers are paying for the

The Nano Repub Confer

July 1 @ UC

device, said Ball.

