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Technology Steven J. Marcus Implant in Ear Aids the Deaf

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AT Kolff Medical Inc. of Salt Lake City, they call it the Ineraid artificial ear. Biostim Inc. of Princeton, N.J., calls its device the Bioear. A joint venture of the House Ear Institute in Los Angeles and the Minnesota Mining and Manufacturing Company currently dominates the field with its House-3M Cochlear Implant. And Nucleus Ltd., an Australian entry in the American market, offers a Multichannel Cochlear Implant.

The four companies, combining advances in medicine and microelectronics, are seeking to provide some hearing to people whose deafness is too profound to be helped by ordinary hearing aids.

The work is based on a new technology that approximates sound signals with electrical impulses delivered by devices implanted in the inner ear.

None of the four products is offered commercially; each is at some stage of clinical evaluation under an "investigational-device exemption" granted by the Food and Drug Administration. But approximately 450 implants have been performed worldwide, and the results are encouraging enough to predict that some deaf people may soon be able to regain some hearing.

For those who are nerve deaf, having suffered damage to the sensory hair cells within the cochlea, or inner ear, that transmit sound to nerve endings and the brain, a cochlear implant can in effect "reconnect the cut wires," says Biostim's president, Lloyd A. Ferreira.

There are 300,000 people in the United States whom specialists consider profoundly deaf; damage to their hair cells is so extensive that hearing aids are useless. And it is estimated that about two-thirds of them could benefit from implants. Two million others have suffered partial impairment of the hair cells and cannot understand speech without a hearing aid, but it is still too soon to say how many could do better with implants.

The devices, which resemble a Sony Walkman, cost about \$5,000. But surgery, hospital charges and therapy raise the total cost to about \$15,000, and for a relatively primitive system. People in the field expect that the size of the device will become smaller, more sophisticated and more expensive, and that its application could expand. "I have absolutely no doubt," Mr. Ferreira says, "that the business will eventually achieve annual sales of \$1 billion or more."

At the moment, says Pieter Halter, executive editor of Biomedical Business International, a journal of the health-care industry, the market is embryonic, with sales in the United States, for research purposes only, of about \$1 million. But he says this figure may exceed \$40 million by 1988. "There will be very rapid growth," he says, "but probably not as rapid as Lloyd predicts."

Experts agree that House-3M was first into the field - its device has been implanted in 380 patients - and could be approved promptly by the F.D.A. once application is made. William F. House, president of the House Ear Institute, estimates that it could be commercial within six to eight months. But although such status would allow this implant to have the market to itself for several years, 3M seems disinclined to rush.

"We are not in this for a quick killing," says Robert J. Oliveira, manager of 3M's Otologic Products program. Greater understanding of the complex hearing process must be gained before the benefits of a device - even a relatively simple one like the House-3M implant - can be assessed. Thus 3M is committed, Dr. Oliveira says, to long-term research that would spare patients from unrealistic expectations and perhaps develop new areas of technology for the company. "To think in terms of a huge market right now," he says, "would weaken the effort."

Another reason for delay could be the limits of the device itself. With a single channel for electrical signals, the perceived sound "sounds like a radio that isn't quite tuned in," Dr. House says. And although it gives the patient the ability to discern "environmental sounds" like footsteps or a siren, and to hear voices, the patient cannot distinguish all the words.

Robert K. Jarvik, inventor of the Jarvik artificial heart and now president of Kolff Medical, says patients have been satisfied so far with single-channel cochlear implants simply because it took them "from nothing to something." These enable them to hear tones and improve their lip-reading, he says, but only multiple-channel systems and other advances in speech-processing electronics can provide something akin to real hearing.

Dr. House acknowledges that multichannel implants seem to advance the technology. The Nucleus system, he says, "is the most complex and sophisticated system available." But he adds that "more sophisticated doesn't mean best," and that clinical trials have yet to show that the approach will deliver on its promise.

Developers of the newer products acknowledge that their confidence, although not without basis, is premature; the Nucleus system has been implanted in 12 patients and the Kolff in only 4. "We bear reasonably good news," Dr. Jarvik says, "but we still have a long way to go."

Yet if clinical trials prove successful, he adds, such products could be "broadly available within two to three years."

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