

Middle Ear Implants Restore Hearing

by Mark Willis



Dr. Robert Goldenberg with models of the implant system.

Concern about the spread of AIDS and other infectious diseases led doctors in the 1980s to look for alternatives to various transplantable human tissues, from corneas to knee bones, saved in hospitable tissue banks. When Robert Goldenberg, M.D., considered the implications for reconstructive ear surgery, he began to design a new type of implant to restore hearing in the middle ear. The result was the Goldenberg Implant System, now manufactured and marketed worldwide by the British health-care giant Smith & Nephew ENT, Inc.

The Goldenberg system includes prostheses in several

basic shapes that can be used to reconstruct the bones of hearing (the hammer, anvil, and stirrup) in the middle ear. Also known as ossicles, these bones transmit sound vibrations from the eardrum to the nerve-lined cochlea in the inner ear. The ossicles can be damaged permanently by repeated middle ear infections, a condition known as chronic otitis media. If left untreated, the condition also can lead to perforated eardrums and nerve damage to the inner ear. When significant hearing loss results, the bones of hearing can be replaced with prostheses that can transmit sound

from outer to inner ear.

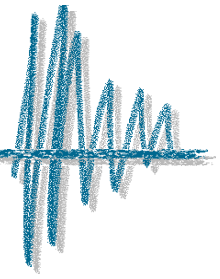
“Middle ear implants restore hearing mechanically with sound vibration,” explains Dr. Goldenberg, professor and chair of otolaryngology at Wright State University School of Medicine. “Hearing loss in the middle ear, unlike nerve deafness, can be corrected surgically, without requiring hearing aids.”

Over the past 25 years, two types of middle ear implants have been used to replace damaged ossicles. The first type is made from human tissue, including ossicles harvested from deceased donors. The second type, known as bioactive implants, is made from synthetic materials. Both

types yield comparable hearing results, according to Dr. Goldenberg. Human tissue implants have the advantage of less frequent rejection by the body’s immune system, but synthetic implants are less likely to transmit infectious diseases.

As Dr. Goldenberg’s design project evolved from drawings to prototypes, he chose a new synthetic material that had just been approved for use in prostheses by the U.S. Food and Drug Administration (FDA). The material is hydroxylapatite, a type of ceramic that resembles porcelain in its texture and density. Prostheses made from it can be used directly against the eardrum without using any other tissue as a buffer. The synthetic material has the added advantage of being easily trimmed and shaped with a knife, enabling prostheses to be modeled during surgery for an exact and precise fit.

Confident of the feasibility of the new implant system, Dr. Goldenberg turned for assistance to Smith & Nephew, a leading manufacturer of medical products used by ear-nose-throat specialists. A computer model of the middle ear developed by the bio-engineering department at Smith & Nephew was used to test the design of each component in the Goldenberg system. The prostheses were refined using CAD/CAM (computer-assisted design/computer-assisted manufacturing) technology. After a year of close collaboration, the Goldenberg



Implant System was ready to test in patients.

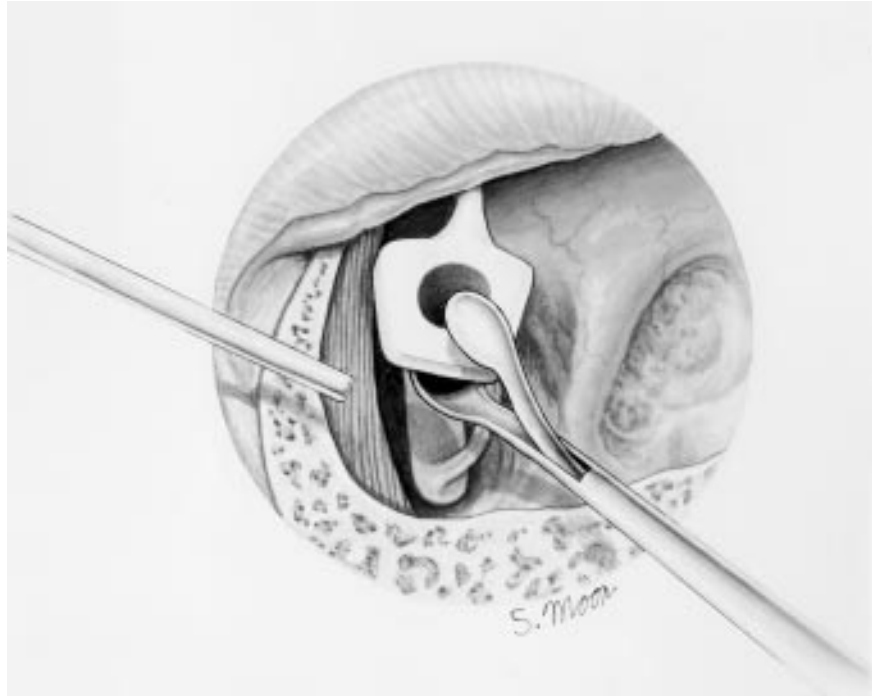
“The very first time we used it, we had good results,” Dr. Goldenberg recalls. “Over time, we have continued to refine the design to get even better results.”

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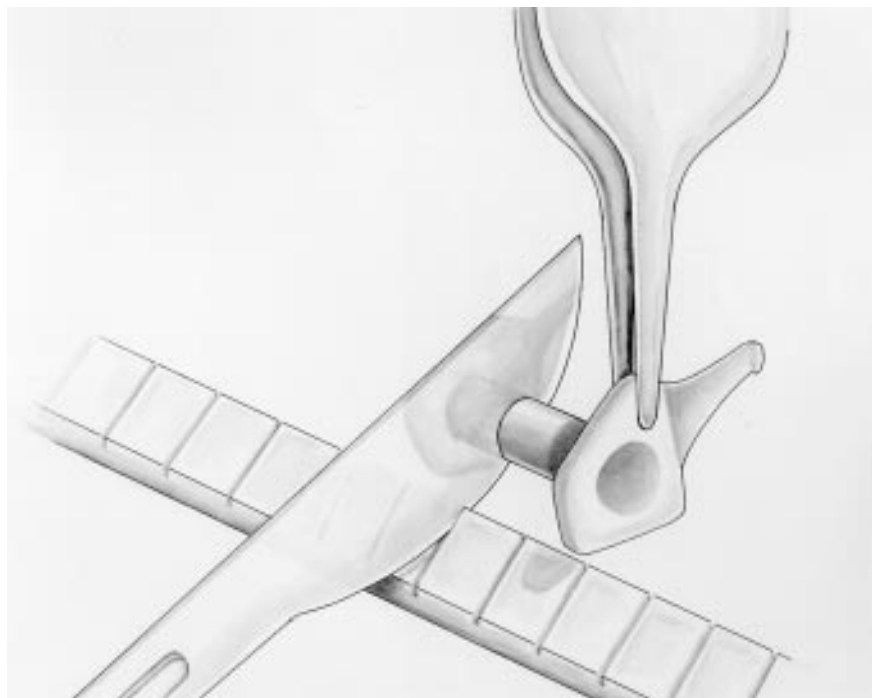
Dr. Goldenberg has used the implant in about 400 of his own patients. “The hearing results have been great,” he says. “In many cases, the prostheses restore hearing completely back to normal. It’s important to note, though, that I don’t use my prostheses for every middle ear reconstruction. There are some cases in which other types of implants work better.”

Simplicity and efficiency have made the Goldenberg Implant System an international leader among middle ear prostheses. Smith & Nephew has sold thousands of the implants worldwide. Ear surgeons report that the ease of selecting and trimming Goldenberg implants can reduce surgery time considerably.

“I’m a perfectionist. My inclination is to continue refining the design,” Dr. Goldenberg says. “Smith & Nephew says ‘no’ for now. Surgeons continue to ask for it because it works fine just as it is.”



Goldenberg incus prosthesis being placed into middle ear.



Cutting the Goldenberg prosthesis to the exact length required.