Otologics Fully Implantable Hearing System: Phase I Trial 1-Year Results

*Herman A. Jenkins, †James S. Atkins, ‡Drew Horlbeck, §Michael E. Hoffer, ¶Ben Balough, †¶George Alexiades, and †||William Garvis

*University of Colorado Denver, Aurora, Colorado; †Florida Ear and Balance Center, Celebration, Florida; ‡Wilford Hall Hospital, Lackland AFB, Texas; §San Diego Naval Medical Center, San Diego, California; †¶New York Eye and Ear, New York, New York; and †||ENT Specialty Care of Minnesota, Minneapolis, Minnesota, U.S.A.

**Objective:** To assess the safety of the Otologics fully implantable hearing system after 1 year of use in a Phase I clinical trial. **Study Design:** Repeated-measures within-subjects design. **Setting:** Procedures were performed in a variety of facilities, including a university, military, and private hospital’s ambulatory surgical center and outpatient clinical audiologic test facilities. **Patients:** Adult patients with bilateral moderate to severe sensorineural hearing loss. **Intervention(s):** Surgical insertion of this prosthesis included an atticootomy to expose the incus, securing the transducer to the mastoid bone, attaching the transducer tip to the incus via insertion into a laser-drilled hole, and postauricular implantation of the microphone/battery/electronics capsule. **Main Outcome Measure(s):** Subjective patient benefit, aided sound field thresholds, and speech discrimination with the subject’s own, appropriately fit, walk-in hearing aid(s) and the prosthesis were assessed. **Results:** There were no pre–post-implant differences noted for bone conduction: slight differences were noted in the pre–post-implant air conduction results \( (p < 0.05) \). These differences were attributed to the healing process and reversed to almost preimplant assessment levels by the third-month evaluation. Pure-tone averages and monaural word recognition scores were slightly better for the walk-in-aided condition \( (p < 0.05) \), whereas the patient benefit scales favored the postoperative implant-aided conditions. Adverse effects of the implant were encountered on 14 occasions after the implantation of the 20 subjects. With the exception of partial device extrusions (that occurred later), all were rectified by the time of initial activation. At the 12-month data collection point, problems that had been encountered by subjects included 1) partial device extrusion (3 subjects), necessitating explantation in 2; 2) loss of external communication (2 subjects), resulting in 1 explantation; and 3) increased charging times beyond 1.5 hours (7), resulting in 3 explantations and 2 patients not using their device while awaiting explantation. **Conclusion:** Phase I trial results provide evidence that this fully implantable device can provide sound amplification to sensorineural hearing loss patients, with performance results similar to the patients’ walk-in hearing aids. **Key Words:** Fully implantable hearing system—Otologics LLC—Phase I clinical trial—Sensorineural hearing loss—Transducer. Otol Neurotol 00:00–00, 2008.

Although conventional hearing aids have improved both cosmetically and technically, only approximately 15 to 20% of the 28 million Americans who have hearing loss severe enough to impact communications use amplification from these devices regularly (1). As the current baby boomer population ages, the hard-of-hearing population is expected to increase (2). Reasons for limited adoption of hearing aids vary among individuals, but perceived poor quality of sound due to feedback, limited frequency response range, ear canal occlusion, pain or irritation, social stigma, and cosmetic issues are frequently cited. In addition, hearing aid wearers report difficulties using their aids in hot, moist climates and during exercise and activities that lead to moisture accumulation in the external auditory canal.

Several teams have sought to overcome these issues with semi-implantable hearing devices that consist of an implantable stimulator and an external speech processor. These devices negate many of the common complaints of conventional hearing aids. Directly driving the middle ear ossicles results in low distortion, wide frequency responses, and limited feedback, all associated with perceived improved sound quality (1,3–9). Recent studies...
have also shown cost-effectiveness of implantable hearing devices for patients unable to wear conventional hearing aids (10). The Otologics fully implantable hearing system incorporates the microphone, speech processor, battery, and stimulating transducer into a prosthesis, which can be totally placed under the skin behind the ear, avoiding many of the fitting and cosmetic issues. It is manufactured by Otologics, LLC, Boulder, CO. The device offers the same freedom and comfort of the natural auditory system, allowing use in environments not suitable for conventional hearing aids such as showering, swimming, and sporting activities. This study is the second in a series of outcome reports for the treatment of adults 18 years or older with moderate to severe sensorineural hearing loss as part of the Phase I, US clinical trial. The earlier report detailed the initial activation results (11).

MATERIALS AND METHODS

The Otologics fully implantable hearing system and the operative procedure have been described in detail in a previous publication (11). Briefly, it consists of four primary components: 1) the implant containing the electronic capsule, microphone, and transducer; 2) the programming system; 3) the charger; and 4) the remote control (Fig. 1). The electronic capsule contains the battery, magnet, digital signal processor, radiofrequency coil, and connector. Signals picked up from the microphone are relayed to the transducer with its tip mounted in a laser-drilled hole in the body of the incus. The transducer translates electric signals into a mechanical motion that directly stimulates the ossicles. An atticotomy is performed, and a bracket is mounted to the cranium. A potassium-titanyl-phosphate laser is used to drill a hole in the body of the incus, and the tip of the transducer is advanced into the hole until contact is confirmed with the loading assist system. The microphone and implant capsule are countersunk into the bone and firmly fixed with bone-anchored sutures.

Using OtoFit Fitting Software, the NOAHlink interface receives signals through a Bluetooth wireless connection and transmits them to the implant via the radio frequency coil. Programming the implant is similar to traditional digital hearing aids. The charger system includes a base station, charging coil, and charger body. The remote control placed over the implanted coil turns the implant on and off and adjusts the volume.

Study Population

Twenty adult subjects, 10 men (4 left and 6 right ears) and 10 women (7 left and 3 right ears), were implanted. Mean age was 62.8 years, ranging from 31.6 to 82 years, with a median age of 64.4 years. Criteria for selection included bilaterally symmetric (within 20 dB) hearing, moderate to severe (40–80 dB) pure-tone or high-frequency pure-tone average hearing loss within the candidacy range (Fig. 2), and NU-6 scores greater than 40% at 80 dB hearing level or 40 dB sensation level in the ear to be implanted. All hearing losses were postlingual at onset, stable, and nonfluctuant, and all patients had previous experience using hearing aids for at least 3 months. Subjects with concomitant disease processes, for example, retrocochlear hearing loss or otitis media, were excluded from the study. Additional information concerning candidacy has been detailed previously (11).

Presurgical audiometric evaluation included unaided and aided (free field) air and bone conduction and speech recognition with the patients’ own “walk-in” hearing aids. In addition, the walk-in hearing aids were verified to be appropriately fit for the patients’ hearing level using probe microphone measurements. All implanted subjects fell within the established fitting range of the implant.

Study Design

The clinical trial was designed and conducted as a repeated-measures, single-subject study with 1 baseline condition. Preoperatively, subjects were evaluated with their own walk-in hearing aids. Postoperatively, subjects were reassessed after the initial activation and 3, 6, and 12 months postoperative. Postoperative implant results were compared with the hearing aid baseline using repeated-measures analyses of variance (general linear model), multiple comparisons, and paired t tests as appropriate. Throughout the study, adverse events were monitored by the study’s sponsor (Otologics, LLC).

The study’s primary dependent measures included standardized measurements of unaided and aided hearing sensitivity, middle ear function, and aided speech perception. Subjective measurements of aided sound quality and self-reported hearing disability completed the audiologic test battery. Aided function

![Otologics fully implantable hearing system](image)

FIG. 1. The Otologics fully implantable hearing system.

Otology & Neurotology, Vol. 00, No. 00, 2008
was assessed monaurally in the ear of implant and binaurally. At surgery, the intraoperative loading assist instrumentation and micrometer advancement of the transducer tip into the laser-made hole allowed proper loading of the ossicular chain.

The procedures were followed in accordance with ethical standards for research using human subjects. The study was conducted under the Food and Drug Administration (FDA) IDE G 040052 and the University of Colorado at Denver and Health Sciences Center COMIRB 04-0579. Each local site obtained institutional review board approval to conduct the study.

RESULTS

After implantation, subjects were activated after an 8-week healing period. Audiologic evaluations were repeated 2 (at activation), 3, 6, and 12 months later.

Adverse Events Associated With the Implantation

Adverse effects of the implant were encountered 14 times after the implantation of the 20 subjects. Some subjects had multiple occurrences. These included fullness or pressure sensation (2), conductive hearing loss (4), lightheadedness (1), tinnitus (1), partial device extrusion (3), and middle ear effusion (3). With the exception of the partial device extrusions (that occurred later), all were rectified by the time of initial activation.

Device Malfunctions and Failures

During the Phase I clinical trial, difficulties were encountered with the fully implantable hearing instrument. The purpose of a clinical trial of a new device is to analyze difficulties that are not obvious in the laboratory. At the
12-month data collection point, problems encountered by subjects included 1) partial device extrusion (3 subjects), resulting in explantation of the device in 2; 2) inability to charge or establish communication (2 subjects), resulting in 1 explantation; 3) increased charging times beyond 1.5 hours (7), resulting in 3 explantations and 2 patients not using their device while awaiting explantation. At the time this article was written, 12 of the 20 patients are actively wearing their devices, 2 of which were not available for the 12-month follow up.

The manufacturer addressed the issues affecting the device communication and charging as soon as they became apparent, but all 20 patients were implanted by the time the problems were discovered. It is expected that all patients in this Phase I trial may experience device communication problems and increased charging times. The FDA has given permission to reimplant the subjects, and 16 of the 17 patients contacted have asked to be explanted and reimplanted with the modified device. Three patients have not been reached at this time.

### Audiometric Test Results

The data presented in this report include preoperative and the 3- (n = 20), 6- (n = 18), and 12-month (n = 10) follow-up evaluations. Although all of the following graphs show mean data, independent of sample size, statistical significance is only calculated for groups of equal number.

Figure 3 presents the preoperative and postoperative air and bone conduction thresholds for each follow-up test session. Although, on average, there were no pre- vs post-implant differences noted for bone conduction, slight differences were noted in the pre- vs post-implant air conduction results at the 2-, 3-, and 6-month evaluations ($p < 0.05$) for all frequencies other than 1,500 and 2,000 Hz. These
Sensory differences were attributed to the healing process and reversed to almost preimplant assessment levels by the 3-month evaluation. By the 12-month data collection, the only differences (p < 0.05) were at 250 and 500 Hz. The sensorineural hearing level of the subjects was unaffected by implantation. Monaural and binaural testing of speech discrimination in the implant ear were made preoperatively and postoperatively using consonant/nucleus/consonant (CNC) words and phonemes and hearing in noise at the 3-, 6-, and 12-month follow-up visits. During monaural stimulation, the contralateral ear was plugged. No significant differences were observed between the patients' own hearing aid and the implant instrument for the binaural condition. Figure 4 presents the averaged data for the monaural condition. No significant differences were noted between the patients' own hearing aid and the implant instrument for the phoneme scores. However, during word score testing, the hearing aid condition was slightly better (p < 0.05) at the 3-month evaluation.

Word scores with the implant decreased at the 6-month evaluation. Lateral radiograms taken of each patient showed significant microphone displacement, although the microphones had been sutured to the bone. The signal processing algorithm for each patient was updated, and the patients were refitted during an "unscheduled" 7-month postoperative visit. Results from this fitting showed improved speech score results equivalent to the "walk-in-aided" condition that decreased slightly at the 12-month follow-up visit.

Speech discrimination in noise was measured by the Hearing in Noise Test (HINT) adaptive procedure. In contrast to the normal HINT scores, lower scores are better. Figure 5 summarizes the HINT adaptive procedure results. During the initial evaluation, scores using the implant were better than the patients’ own walk-in aid. At 6 months, the performance deteriorated in both CNC and adaptive HINT scores. After refitting, adaptive HINT scores dramatically improved and remained better at 12 months.

Functional gain is used frequently to measure improvement with amplification. The implant performed significantly less well than the patients’ own hearing aid.

**FIG. 6.** Averaged postoperative results for all follow-up questionnaire data compared with the patient’s walk-in hearing aids. 1 indicates very dissatisfied; 2, dissatisfied; 3, neutral; 4, satisfied; and 5, very satisfied as answered by each subject.
aid ($p < 0.05$) for all frequencies but 4,000 and 6,000 Hz at all test sessions.

Each subject completed subjective questionnaires before and after implantation. The questionnaire included 19 different conditions and the Abbreviated Profile of Hearing Aid Benefit (APHAB). A scale of 1 to 5 was used, in which 1 is very dissatisfied; 2, dissatisfied; 3, neutral; 4, satisfied; and 5, very satisfied. The averaged results for the postoperative questionnaires are presented in Figure 6. The patient’s subjective evaluations demonstrated that the implant performed at least as well as and, for many of the measures, substantially better than their preimplant hearing instrument in virtually every category. Specifically, subjects thought that the implant was exceptional in expected areas such as visibility to others and occlusion. These are major factors in subjects’ use of amplification and were anticipated outcomes. Some areas indicated as high performance such as sound quality, performance in noisy situations, ability to hear soft sounds, and comfort of loud sounds, among others, were unexpected. At the 6- and 12-month data points, the patients were less impressed with the implant with regard to battery life and ease of charging the battery. This related to the length of time that they needed to charge the implant.

The APHAB includes 4 subscales expressed as percent of problem occurrence. These include 1) ease of communication, 2) reverberant listening conditions, 3) background noise, and 4) aversiveness to sounds. In conditions ease of communication, reverberant listening conditions, and background noise, less positive values indicate a preference, and in aversiveness to sounds, a less negative number indicates a preference. Patients preferred the implant device to their own aid for all conditions (Fig. 7). Patients reported their daily usage of the device. At the 3-month data point, 17 (85%) stated they used their device every day. Of the 3 who did not, 1 reported that he sometimes did not use it on weekends when alone; 1 reported only using the device when he needed it, similar to how he used his own hearing aid with similar benefit; and the third did not use it daily because of feedback.

At the 6- and 12-month data points, 78 and 55% reported using the implants on a daily basis, respectively. The primary reason stated for not using the implant was to conserve battery life for the times when the implant was most needed, such as at work. At the 3-month data point, more than 85% of the patients used the implant for more than 8 h/d, whereas at the 12-month data point, more than 65% of the patients were using the implant more than 8 h/d. Because the implant can be used during charging, 65% reported using the implant during charging at the 3-month data point, whereas at the 6- and 12-month data points, only 45% used the implant while charging.

All patients charged the implants while at home, with 50% recharging at work or while in the car. Greater than 70% were able to use cell phones, regular phones, and cordless phones with the implant, with cordless phone use being the most prevalent and cell phone being used the least. More than 50% of patients reported bathing/showering while using their implant, whereas only 1 consistently slept with their implant on all night.

**DISCUSSION**

This Phase I study focused on the safety of the fully implantable hearing device. Most issues encountered associated with the surgical procedure were a routine part of the recovery process. Of concern is the 3 devices that partially extruded. One occurred at 3 months and 2 at 6 months postimplantation. One was revised with a minor procedure in which the transducer lead was sutured to underlying tissue and the skin closed primarily. This patient healed uneventfully, and the patient is still using the device. The
other 2 underwent revision surgery, with healing occurring before activation. However, both reextruded a few weeks later and were eventually explanted. Extrusion with any implantable device is a concern particularly once exposure and contamination occurs. The implant package is relatively large, and caution should be used in ensuring sufficient thickness of skin in areas covering the device. A natural thinning of the skin occurs after implantation, and any thinning at the time of surgery should be very conservative. Implantation in patients with thin or friable skin should probably be avoided at this point because the risk of extrusion is potentially increased.

The change in air conduction thresholds would be predicted as part of the mass loading effect on the incus. This is similar to that observed in patients undergoing ossicular reconstruction with residual conductive hearing loss.

An interesting finding in testing postoperatively was the failure of demonstration of equivalent or improved functional gain. This is inconsistent with the results from CNC word and phoneme testing, the adaptive HINT scores, and the questionnaire and APHAB results. Warble tones were used to measure functional gain testing. Early investigations indicated that the noise reduction circuitry algorithm interferes with accurate measures of functional gain, canceling out the free field signal.

At the 6-month testing, significant deterioration of speech perception occurred. Several patients were noted to have migration of their processors and microphones despite having been countersunk into the bone and fixed with a bone-anchored suture. To accommodate the technology necessary for a fully implantable device, the implant capsule must be relatively large. Because of its size, special considerations must be made during the bone bed site selection for both the capsule and the microphone. Initially, both the manufacturer and the investigators underestimated the necessity for a deep bone bed and secure fastening of the microphone and capsule to the cranium. To remedy this, the manufacturer has improved the implant design by placing titanium straps on both the implant capsule and microphone through which a bone screw can be placed to anchor the devices firmly to the cranium for Phase II.

Microphone placement and attachment to the cranium are critical for patient performance. There are 3 convenient microphone placement locations, in the temporalis region (superior and anterior to the external auditory canal), directly posterior to the external auditory canal on the mastoid, and the mastoid tip, and the microphone placement was not controlled for in this study. The microphone is relatively insensitive to the absolute amount of tissue over its diaphragm but is very sensitive to changes in tissue thickness over time. Because movement and changes in the thickness of the skin in areas of the mastoid in response to head movement or contraction or due to microphone migration, the calibration factor will no longer be correct, potentially causing the patient to experience feedback. In some cases, the initial fitting with Phase I version of the digital processing algorithms was inadequate to accommodate these changes and resulted in feedback that was mitigated by reducing the gain.

Adjustment of the digital processing algorithms resulted in significant improvement. Phase I studies are not permitted to make adjustments for improved performance without FDA approval. Because the implant has a powerful signal processor and can accept new fitting algorithms, it is anticipated that during the Phase II efficacy study, when the patient fittings can be optimized for gain and speech understanding, functional performance results will significantly improve.

After initial acclimatization with the implant, there were no anatomic sounds (muscle movement, heart beat, chewing, speaking) that bother the patients. Anecdotally, patients preferred the implant to their hearing aids in the wind, stating that the implant microphone did not pick up wind noise like their previous hearing aids. One woman with shoulder-length hair reported “hair noise” as her hair moved over her microphone as it brushed across her shoulders. Once her hair grew out over her shoulders, she no longer reported these sounds.

The inability to charge and communicate with the implant was noted in 2 subjects, requiring a change to the system. It seemed that this was caused by the subjects’ lack of access to their charger for a long period of time, resulting in difficulty in getting the instrument to charge. The implant circuit board has been modified to allow instrument charging even if it has not been charged for quite some time. Increasing charging times were encountered by more than a third of the subjects. Prolonged charging times have been related to an adhesive containing silicon, with resultant off-gassing and deterioration of capacitors in the electronics capsule. This has been changed to a new compound, and similar prolonged charging have not reoccurred.

The Otologics fully implantable hearing system has received the CE mark, allowing it to be sold in Europe for the treatment of sensorineural hearing loss, and is currently in Phase II trials in the United States. At the time this report was written, more than 50 subjects have been implanted in the United States and Europe with the modified device, some with 8 months of use. There has been no evidence of the appearance of the previous problems noted in the Phase I trial.

CONCLUSION

This Phase I clinical trial for evaluating the safety of the Otologics fully implantable hearing system has shown its feasibility and lack of deleterious effects on native hearing. Significant challenges in its clinical application have been encountered, and the company is addressing these issues in design revisions. Patient subjective questionnaires demonstrated improved naturalness of sound and functional hearing that are similar to their baseline hearing aids.
REFERENCES