Initial Clinical Experience With a Totally Implantable Cochlear Implant Research Device

*†Robert J. S. Briggs, ‡Helmut C. Eder, †‡Peter M. Seligman,
*†Robert S. C. Cowan, †‡Kerrie L. Plant, ‡James Dalton, ‡David K. Money,
and *†‡James F. Patrick

*The University of Melbourne Department of Otolaryngology; †The Co-operative Research Centre for Cochlear Implant and Hearing Aid Innovation, Melbourne; and ‡Cochlear Limited, Sydney, Australia

Objective: To evaluate the effectiveness and issues associated with a research totally implantable cochlear implant (TIKI).

Study Design: Limited patient trial.

Setting: Tertiary referral center.

Patients: Three adult human subjects with severe-to-profound sensorineural hearing loss.

Interventions: Subjects were implanted with a research TIKI developed by Cochlear Limited and the Co-operative Research Centre for Cochlear Implant and Hearing Aid Innovation. The TIKI has a lithium ion rechargeable battery, a package-mounted internal microphone, and sound-processing electronics that enable the use of “invisible hearing” without the use of an external device. The TIKI also functions with an external ESPrit 3G sound processor as a conventional cochlear implant. The standard surgical technique was modified to accommodate the larger device package. Postoperatively, subjects used TIKI in both invisible hearing and the conventional ESPrit 3G modes.

Main Outcome Measures: Device use was recorded in both invisible hearing and ESPrit 3G listening modes. Performance of the internal battery and microphone was assessed over time. Psychophysical MAP data were collected, and speech perception was measured at 1, 3, 6, and 12 months postoperatively in both listening modes.

Results: There were no surgical or postoperative complications. All subjects use both invisible hearing and conventional ESPrit 3G modes. Speech perception outcomes for all patients showed improvement from preoperative scores. As a consequence of the reduced sensitivity of the implanted microphone, speech perception results using the invisible hearing mode were significantly lower than the ESPrit 3G mode. Subjects reported some body noise interference that limited use of the invisible hearing mode; however, all continue to use the invisible hearing mode on a limited daily basis. The rechargeable battery functioned well, with a cycle time indicating the low-power implant design is effective and will deliver long battery life.

Conclusion: This study demonstrates that the challenges in developing a safe and effective TIKI can be overcome. Three subjects implanted with the research TIKI all reported benefit from routine use. For each subject, hearing outcomes using invisible hearing mode were not as good as when using the external ESPrit 3G sound processor in the conventional mode. Key Words: Cochlear implants—Totally implantable.


The multichannel cochlear implant has been extremely successful in providing hearing restoration for patients with severe-to-profound sensorineural hearing loss (HL). Current cochlear implant systems require the user to wear an external device with battery, microphone, sound processor, and transmitting coil to power and control the internal device. The use of an externally worn processor has denied recipients the use of the implant system in some environments, for example, when participating in water sports or when sleeping. A long-term goal of cochlear implant research is to provide a totally implantable cochlear implant (TIKI) that will allow the recipient to access invisible hearing without the need for any externally worn components so as to overcome these situational limitations.

The development of an implantable microphone, rechargeable battery, and low-power sound processor presents considerable challenges. The microphone must be sensitive and either contained within the hermetic seal

Address correspondence and reprint requests to Robert J. S. Briggs, M.B.B.S., F.R.A.C.S., Department of Otolaryngology, University of Melbourne, 32 Gisbourne St., East Melbourne, Victoria 3002, Australia; E-mail: rjbriggs@netspace.net.au

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of the implant package for direct transcutaneous sound transfer or constructed to enable transmission from the ossicular chain or tympanic membrane. The battery must be small, rechargeable, and must have a long life. It must be safe, with no risk from heat production or leakage, even in the event of failure of the other components. The sound processing system that is incorporated into the internal device must be efficient to minimize power consumption, and the TIKI must be small enough for implantation with conventional surgery. In addition, recharging the internal battery must be convenient for users in their everyday lives.

The TIKI project’s aim was to explore the potential of a totally implanted device and to discover and evaluate limitations of the research technology used, including the seriousness of body noises as a problem. As noted, the TIKI was designed to provide access to hearing in environments previously not available to cochlear implant recipients. In addition, a totally implanted device can provide cosmetic advantages over the conventional implant with its externally worn components. It was expected, however, that both the nature and quality of the signal from any implanted microphone would be inferior to that from the ear-level directional microphone used in the ESPrit 3G. A principal aim of the study was to assess this difference.

MATERIALS AND METHODS

Device Description

The research TIKI system was designed to provide a conventional hearing mode (i.e., using an ESPrit 3G sound processor) and the option of invisible hearing. The TIKI allows easy switching between these modes. This capability allowed for a within-subject comparison of the benefits and limitations of invisible hearing versus conventional hearing mode.

With the ESPrit 3G in place, the implant functions using the standard external hearing mode; when the ESPrit 3G is removed, the device switches into invisible hearing mode. An external controller with transmitting coil can be used to turn invisible hearing on and off and to adjust the invisible hearing sensitivity. The TIKI battery can be charged either by the external controller or the ESPrit 3G.

In the invisible hearing mode, the sound processing system supports the advanced combination encoding, spectral peak extraction, and continuous interleaved sampling strategies at stimulation rates up to 12 kHz. To minimize electrical and body noise, the input processing included several new compression algorithms and channel-specific noise reduction.

Engineering

The complete TIKI is shown in Figure 1A and with the CI24RE Freedom for comparison (Fig. 1B). The packaging technology and electrodes used in the device are the same as those in the commercial Cochlear, Ltd. devices. However, the signal processor and stimulator electronics are specially designed using a proprietary application-specific integrated circuit. The subcutaneous microphone diaphragm can be observed just below the connections to the receiver coil.

The package dimensions are 7.5 × 28 × 28 mm. The total length of package and antenna is 60 mm. This compares with the CI24RE package size of 6.7 × 22 × 22 mm and length of 51 mm. Although the TIKI prototype has been developed for use only in adults, the package pedestal size and, thus, the bone well necessary is equivalent to the well used for ceramic case implants, and so it can potentially be used in children.

Microphone

Implantable microphones have been previously developed for implantable hearing aids. Notable examples are those developed by Implex, Envoy Medical (previously St. Croix Medical), and Otologics. Spindel (1) has reviewed these devices in more detail. To minimize the technical risk associated with the microphone, TIKI uses a subcutaneous microphone based on a conventional electret microphone that incorporates a titanium, diaphragm-covered cavity, included within the body of the stimulator.

Battery

The battery used in the device of the present study is a rechargeable lithium ion cell. Like all other major subsystems in the implant, the battery design was analyzed using a failure mode and effect analysis to analyze possible modes of failure. This was used to develop a comprehensive qualification plan. The battery then passed qualification tests that included impact tests, heat generation, and environmental testing. No failures
were observed after exposure to high and low temperature, high and low pressure, mechanical shock, vibration, and thermal shock.

**Preliminary Testing and Safety Studies**

The TIKI device was constructed using the same biocompatible materials as the Freedom implant and using Cochlear’s manufacturing and sterilization methodologies. In vitro and animal studies were undertaken to assess the function and optimize the design of the totally implanted microphone. Extensive parametric tests and safety studies were performed to assess the battery. Under the assumption that TIKI would need to operate in invisible mode for at least 10 h/d using the maximal stimulation rate, the battery was verified to provide a minimum of 1,000 charge cycles. Once the battery has ceased to function, invisible hearing will no longer be available to the subject; however, TIKI will still function in conventional mode with the external sound processor.

**Surgical Procedure**

Because TIKI is larger than the existing Nucleus cochlear implants, a cadaver study was undertaken to examine surgical technique and device placement. The minimally invasive surgical technique was modified to accommodate the larger device package. The usual incision was extended by approximately 3 cm, a posteriorly based fibroperiosteal flap was raised, and a larger well was drilled using a template to create an accurate fit for the device pedestal. Dura was exposed in part of the well; however, exposure was minimized to reduce transmission of intracranial pulsation. Care was also taken not to traumatize the peristeum and scalp flap overlaying the site of the package and microphone in the hope of minimizing fibrosis that might affect sound transmission.

**Clinical Evaluation**

Three adult subjects with severe-to-profound sensorineural HL were recruited and implanted with the TIKI device at the University of Melbourne Cochlear Implant Clinic. All subjects had a postlinguistic onset of bilateral severe-to-profound sensorineural HL. The subjects were recruited on the basis of their hearing history and willingness to participate in the research study. Before involvement in the study, the potential limitations of the invisible hearing research device were carefully explained to each patient. Demographic details are described in Table 1.

After the normal clinical protocol in the Melbourne cochlear implant clinic, each subject’s cochlear implant was activated after approximately 2 weeks of postoperative recovery. Extensive investigation was conducted to optimize the device fitting. Each subject was programmed using a stimulation rate of 500 Hz per channel and with 8 maxima selected during each analysis period, that is, using a total stimulation rate of 4 kHz. A range of diagnostic measurements was taken to characterize the performance of the device, including the microphone frequency response, electrode voltage measures, and measures of battery functionality and characteristics.

The internal microphone frequency response was obtained with the subject seated in the sound field in a sound-treated room. A speaker presented continuous pink noise at a level of approximately 65 dB sound pressure level (SPL). The internal microphone signal was streamed from the implant via telemetry. The overall response of the implanted microphone was calculated by subtracting the response of a reference microphone (placed near the implant site) from the streamed-out spectrum. Battery testing showed that battery autonomy of 35, 23, and 32 hours was available at the subjects’ operating stimulation rates of 4 kHz. From this calculation, the expected battery life of the TIKI is approximately 6 years.

Device programming was conducted using research software specifically designed for the TIKI. Threshold and comfortable levels were measured on each electrode using biphasic stimulus pulse trains of 500 ms duration presented at a stimulation rate of 500 Hz. The ESPrit 3G program was adjusted with live-voice input to achieve a comfortable listening level on the clinically recommended sensitivity setting of 5 on the processor dial. At this setting, the automatic gain control of the processor is activated at an input level of 64 dB. Adjustment to channel gains, base level, microphone preemphasis, sensitivity setting, and invisible hearing threshold and comfortable levels were used to optimize the invisible hearing listening mode. The programming procedure varied significantly over time, with adjustments being made to obtain the best acoustic-aided sound field thresholds within the tested range while maximizing the effect of internal noise. Sound field thresholds, obtained with an ascending-descending audiometric procedure with steps of 5 dB, were measured at the 1-, 3-, and 6-month evaluation sessions. The warble tones (centered at 250, 500, 1,000, 2,000, 3,000, and 4,000 Hz) were sinusoidal carriers modulated with a triangular function over the standard bandwidths recommended for use in the sound field by Walker et al. (2). The modulation rate was 10 Hz.

Postoperative clinical assessments were conducted at 1, 3, 6, and 12 months after initial device activation. At each evaluation, speech perception using both the ESPrit 3G and invisible hearing was tested. Open-set monosyllabic consonant-nucleus-consonant (CNC) words were presented in quiet and open-set City University of New York (CUNY) sentences in multitalker babble. All material was recorded with a female native Australian speaker. The monosyllabic words were research lists developed by the authors on the basis of the original CNC word lists from Peterson and Lehiste (3) having 50 words per list and a CNC structure. The lists were scored as the percentage of whole words correct. The CNC words were presented in quiet at a level of 60 dB SPL. The sentences were based on those developed by the City University of New York comprising lists of 12 sentences containing 102 words scored as percent correct (4). The presentation level for the CUNY sentences was 65 dB.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Sex</th>
<th>Age (yr:mo) at implantation</th>
<th>Duration (yr) of severe-to-profound hearing loss (implanted ear)</th>
<th>Cause</th>
<th>Date of initial activation (d/mo/yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>45:9</td>
<td>10</td>
<td>Ménière’s disease</td>
<td>20/10/2005</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>41:2</td>
<td>4</td>
<td>Ménière’s disease</td>
<td>20/12/2005</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>59:10</td>
<td>6</td>
<td>Progressive, idiopathic</td>
<td>02/02/2006</td>
</tr>
</tbody>
</table>

F indicates female; M, male.
The signal-to-noise ratio (SNR) for testing in noise was +5 dB for Subjects 1 and 2, and ranged from +8 to +6 dB for Subject 3, with the SNRs being selected to prevent floor and ceiling effects. The competing noise consisted of a recorded 4-talker babble that was superimposed and offset in time to create 8-talker babble. Both sentences and noise were presented from the same loudspeaker. Test items were presented once, and no feedback was provided to the subjects regarding the correctness of any response. All evaluations were conducted in a sound-attenuated booth using recorded materials (on compact disc), with the subjects seated at 0 degrees azimuth to the loudspeaker. At each evaluation, there were 2 lists of CNC words and 3 lists of CUNY sentences presented for each listening mode.

RESULTS

There were no surgical or postoperative complications. Wound healing was uneventful despite the larger device package. After initial activation and programming, all subjects were able to successfully use the device in both the invisible hearing and ESPrit 3G listening modes.

The subcutaneous internal microphone provided reasonable high-frequency response as shown in Figure 2. In general, the responses increased at 6 dB/octave up to approximately 2,600 Hz and then dropped. This response was partially compensated in the signal processing. Both the individual channel gains of the band-pass filters and the minimum SPL at which stimulation was delivered were adjusted. Figure 3 shows invisible hearing sound field thresholds obtained using warble tones (at frequencies 250, 500, 1,000, 2,000, 3,000, and 4,000 Hz) at 6 and 12 months after initial activation with each subject. Mean invisible hearing thresholds, when averaged across the tested frequencies, were 29, 42, and 37 dB hearing loss (HL) for Subjects 1, 2, and 3, respectively. Sound field thresholds for all subjects were within the range 15 to 25 dB HL for all frequencies when using the ESPrit 3G sound processor.

Speech perception was improved in all subjects compared with preoperative scores; however, it was better in the conventional hearing mode (ESPrit 3G) than in the invisible hearing mode. Figure 4 shows mean percent correct whole word scores for CNC words presented in quiet for the group and for each individual subject. Similar data for CUNY sentences presented in noise are shown in Figure 5. Mean CNC word scores with the
ESPrit 3G (at the 12-mo evaluation session) were 82, 64, and 84% for Subjects 1, 2, and 3, respectively, measured at the conversational speech level of 60 dB SPL. Testing in noise was conducted with a SNR of +5 to +6 dB SNR to prevent ceiling effects and to enable comparison of ESPrit 3G and invisible hearing modes. Although data were not analyzed statistically due to the limited subject numbers, the group mean CNC word scores for ESPrit 3G and invisible hearing were 77% and 33%, respectively. A similar finding was observed for testing in noise, with the group mean score being 72% for ESPrit 3G and 34% for invisible hearing. Results were similar across subjects.

Figure 6 shows the hearing performance (in both listening modes) over time for each subject for monosyllabic CNC words presented in quiet at the 1-, 3-, 6-, and 12-month evaluation sessions. Each data point was the average of 2 word lists. As expected, there was a general trend for performance to improve over time with both function modes. The improvement for invisible hearing scores for Subjects 1 and 3 between the 3- and 6-month evaluation is likely to be related to the improvement in aided thresholds obtained as a result of improved device programming. Mean aided thresholds, when averaged across the range of tested frequencies, improved from 39 to 29 dB HL for Subject 1 and from 43 to 37 dB HL for Subject 3 between these 2 evaluation sessions. No change was observed for Subject 2 over this time, with the mean aided threshold measure being 42 dB HL at both intervals. The inability to improve aided threshold for Subject 2 is possibly related to this subject having a thicker scalp flap and, thus, reduced sensitivity of the implanted microphone. It was not possible to estimate the level of learning and familiarization effects with invisible hearing due to the significant programming changes and processing improvements that were made over the 12-month period.

All subjects reported benefit from use of invisible hearing. The degree of use of this listening mode and the reports of body noise varied across subjects. Subject 1 uses invisible hearing mode only when necessary. She finds invisible hearing particularly useful when sleeping so she can hear her children during the night. She tends to only use this mode when she is the only adult in the house. Subject 2, however, switches between the ESPrit 3G and invisible hearing listening modes throughout the day and reports that he is never without hearing. He uses invisible hearing in the morning while showering and eating breakfast and while doing physical work, for example, gardening, at home. He also uses invisible hearing while sleeping. When working and communicating during the day, he uses the ESPrit 3G. Similarly, Subject 3 uses invisible hearing during the day when he is at home but changes to ESPrit 3G when going out. He has been unable to sleep with invisible hearing due to the noise created by breathing and swallowing and does not have any particular need to persevere with this to see whether he can adjust to the body noise.

**DISCUSSION**

This study has demonstrated that many of the challenges of developing a safe and effective TIKI system can be met. The TIKI has enabled subjects to use invisible hearing in situations where they could not normally use their cochlear implant. From a technical design viewpoint, no problems were encountered with use of the lithium ion battery, and the cycle time indicates that the TIKI low-power design is effective and will deliver a long battery life. No difficulties were encountered with
recharging of the battery or with switching between invisible hearing and conventional hearing modes. The recharging time from fully flat to fully charged with the invisible hearing processor running is 3.7 hours. It was not recommended allowing the battery to become flat because charging for approximately 1 h/d will prolong battery life. In practice, the charger was rarely used because the ESPrit 3G external processor keeps the battery charged to the top third of its capacity. The subcutaneous microphone located in the implant package provided a reasonable high-frequency response and addressed biosafety issues. The TIKI has limitations in that the internal microphone function has marginal sensitivity, with speech understanding being significantly poorer in the invisible hearing mode and with significant body noise interference also limiting the use of invisible hearing.

The subcutaneous microphone approach has been used by Otologics in the middle ear transducer device where the microphone is mounted behind the pinna. Another approach, by Implex in the totally implantable cochlea amplifier, used a subcutaneous microphone implanted in the ear canal wall. This location makes use of the acoustic properties of the pinna but is surgically challenging because the skin of the ear canal is very thin, and migration and extrusion of the device are a risk. Preliminary results of the totally implantable cochlea amplifier have been reported by Zenner et al. (5).

A more adventurous approach is the middle ear microphone that makes use of the tympanic membrane and other middle ear functions. From a surgical and mechanical engineering point of view, these devices are more complicated. They benefit from, but also depend on, near-normal middle ear function. They may provide better rejection of body noise. This approach is used in the Envoy Medical Esteem device (6). Another possibility would be the use of a cochlear hydrophone. This approach requires all middle ear functions and partially includes the cochlea. The pressure variations in response to sound are detected in the fluid behind the oval window by a form of hydrophone. This approach had been disclosed in a patent (7).

Despite the limitations of the subcutaneous microphone, the TIKI provided situational communication benefits to all patients that were additional to those available from use of their body-worn ESPrit speech processors. Future development of the TIKI to improve microphone performance may include mechanical isolation against vibration and techniques to cancel body-borne noise by means of multiple transducers or accelerometers. Such techniques have been described by Bauman and Leysieffer (8). Alternative methods can involve the use of middle ear or intracochlear microphones as described above.

**CONCLUSION**

Three subjects have been successfully implanted with a TIKI designed specifically for research purposes. The TIKI system has successfully demonstrated the effectiveness of a number of new features not previously used in conventional cochlear implants. The results from this study provide a sound basis for continued development of TIKI technology.

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**REFERENCES**