Design for an inexpensive but effective cochlear implant

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Widespread application of cochlear implants is limited by cost, especially in developing countries. In this article we present a design for a low-cost but effective cochlear implant system. The system includes a speech processor, four pairs of transmitting and receiving coils, and an electrode array with four monopolar electrodes. All implanted components are passive, reducing to a minimum the complexity of manufacture and allowing high reliability. A four-channel continuous interleaved sampling strategy is used for the speech processor. The processor and transmission link have been evaluated in tests with a subject previously implanted with the Ineraid electrode array and percutaneous connector. A prototype of the link, consisting of four pairs of transmitting and external receiving coils, was used, with the outputs of the receiving coils directed to four intracochlear electrodes through the percutaneous connector. The subject achieved speech reception scores with the prototype system that were equivalent to those achieved with a standard laboratory implementation of a continuous interleaved sampling processor with current-controlled stimuli. (Otolaryngol Head Neck Surg 1998;118:235-41.)

The cochlear implant is the only medical intervention that can restore partial hearing in cases of profound sensorineural deafness. More than 12,000 deaf people have received and benefited from the cochlear implant worldwide since 1960.[1] In contrast to earlier single-channel cochlear implants, which served mostly as an aid to lipreading,[2] recent multichannel cochlear implants incorporating advanced speech-processing strategies have resulted in significant open-set speech-recognition performance for a majority of implant listeners.[3-5] The high performance of the cochlear implant also is associated with a high cost; a typical cochlear implant costs $15,000 to $25,000 plus an additional $20,000 to $30,000 for presurgical screening, surgery, and postsurgical rehabilitation.[6]

Unfortunately, the high cost of these commercially available cochlear implants is prohibitive for deaf people in developing countries, where more than 80% of the world population resides. China is one such country, with a population of 1.2 billion people. A 1990 survey indicated that the number of profoundly deaf adults and children in China approximated 5.6 million. The same survey projected that about 30,000 children with profound deafness would be added to this number each year. On the other hand, the average annual personal income is only about $500. Similar situations are present in other developing countries in Asia, Africa, South America, and Eastern Europe.

Several implant systems have been developed with the specific aim of driving down the cost of manufacture. As of 1995, three single-channel systems had been developed and applied in China.[7] All were manufactured in China and sold for 700 to 1000 yuan, roughly $100. Although these systems are inexpensive, their utility generally is limited to providing an awareness of environmental sounds and as an aid to lipreading.[8,9] Recognition of speech from open sets with hearing alone is rare among these single-channel implant users and, where present, is quite modest.

An apparent cost-performance gap is noted here: the effective multichannel implants in the West are too expensive to afford for the deaf people in third-world countries, whereas the inexpensive single-channel implants developed in China are only minimally effec-

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tive. To help bridge this gap, we, as an expert panel from the United States and Canada, were invited to the 1993 Zhengzhou International Conference on Cochlear Implants and Linguistics, in Zhengzhou, China, Oct. 25-28, 1993. The conference was organized by Min-Ming Dong, MD, Professor at the Henan Medical University and one of us (F.G.Z.). The conference attracted approximately 130 physicians, scientists, and engineers, including representatives from most centers in China involved with the development or clinical application of implant systems. Presentations by and informal interactions with Chinese colleagues helped members of the invited panel understand the requirements of an implant system that would be suitable for widespread use in that country. The purpose of this article is to present the recommendations of the panel for the design of such a system. A preliminary report of recommendations was presented at the recent International Cochlear Implant Speech and Hearing Symposium in Melbourne, Australia.[10]

DESIGN CONSIDERATIONS

Key requirements for the design included (1) low cost of manufacture, (2) a device capable of providing open-set speech recognition with hearing alone, and (3) a device that is simple to implant, fit, and maintain.

Low Cost

Our colleagues in China suggested that a cost of 5000 to 30,000 yuan (approximately $600 to $3600) would be appropriate. We note that surgery and other medical costs are not included in this consideration, because those costs are quite low compared with Western standards and are generally funded through a separate government agency or a patient's work group. To stay within this range and to be able to manufacture the device with locally available technology, we first ruled out the possibility of using active internal components. Such components require complex procedures for the design and fabrication of the custom integrated circuit used in the implanted receiver. They also require expensive and complicated hermetic sealing and feedthrough technology to protect the implanted electronics. The decision not to use implanted electronics left only two possibilities: either a percutaneous plug interface or a passive, coil-coupled transcutaneous interface. The percutaneous plug was not recommended due to a serious concern about a greater probability of infection with this system in rural areas, where the frequency of checkups can be quite low. A coil-coupled transmission interface would have to be passive to avoid hermetic sealing. Finally, a monopolar electrode array was preferred to a bipolar electrode array because (1) there is no evidence to date that bipolar stimulation provides better speech recognition than monopolar stimulation, and (2) monopolar stimulation requires lower currents and voltages to produce a given loudness level, thereby extending battery life.

High Performance

Low cost should not come at the expense of performance. The low-cost implant must allow a majority of users to enter or reenter occupations requiring at least some recognition and understanding of speech with hearing alone. The goal of high performance is to provide levels of speech recognition approaching those of the newest implant systems manufactured in the United States, Europe, and Australia. A relatively simple type of speech processor used in several of the new systems is based on the continuous interleaved sampling (CIS) strategy, first described by Wilson et al.[3] Results of recent studies with the CIS and related processors have demonstrated large improvements in speech reception scores with increases in the number of processing channels up to four.[11-13] Further increases in the number of electrodes can produce further gains for some patients, but four generally is the point of diminishing returns. These findings with implant patients are consistent with the results of acoustic simulation studies conducted by Shannon et al.,[14] which show that three or four independent channels can provide nearly perfect speech-reception performance when speech envelope information is properly represented in listeners with a fully intact peripheral auditory system. Taken together, these various results suggest that relatively high levels of performance can be obtained with a CIS processor with four channels of processing and stimulation. A smaller number certainly would produce decrements for some patients. A larger number would preclude practical use of a passive coil transmission system, as described below, and probably would not produce large gains in performance for most patients.

Simple Fitting and Maintenance

Appropriate surgical implantation, audiologic fitting, and device-maintenance procedures are critical to maximize the benefit of cochlear implants. Fitting and maintenance normally are performed by trained audiologists and biomedical engineers in the West. In developing countries, however, the shortage of these trained professionals is a serious concern. In the long run, we hope and expect the number of such professionals will grow. To serve the short-term need, we propose to fix most processor parameters at preset values while allowing only adjustments in sensitivity gain and overall volume control. The fitting system for such a device requires

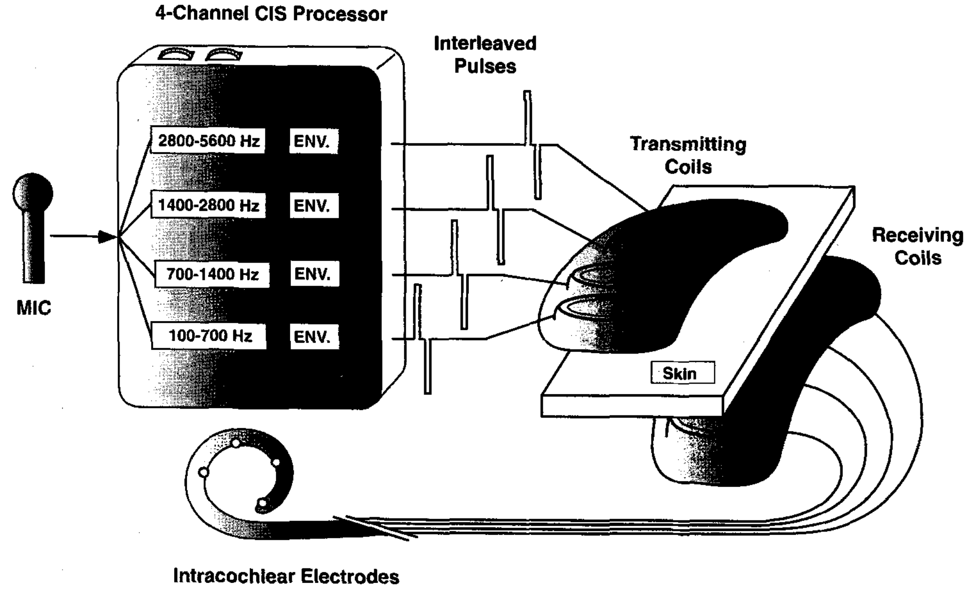


Fig. 1. Schematic illustration of proposed system. *MIC*, Microphone; *ENV.*, envelope.

only manual adjustment of each channel's threshold and dynamic range.[15] The external processor and coil interface must be highly reliable because the homes of many of the anticipated implant users would be far from the implanting center, limiting opportunities to fine tune the device and detect and repair failed devices.

CONSENSUS OF THE EXPERT PANEL

An overview of the recommended system is presented in Fig. 1. The system combines current designs for the speech processor and the intracochlear electrode array with older technology for the transcutaneous transmission link.

Speech Processor

The four-channel speech processor uses a CIS strategy, as noted above. Speech sounds are divided into four frequency bands (or channels) with fixed bandpass frequencies. The temporal envelope in each channel is extracted with a full-wave rectifier followed by a low-pass filter. The cutoff frequency of the low-pass filter is set at 200 Hz to allow maximal transmission of temporal envelope cues while avoiding aliasing when a relatively low carrier rate is used (aliasing is a type of digital sampling distortion[16]). The extracted envelope is then applied to a logarithmic circuit that compresses a 40 dB range of acoustic amplitude to a much narrower electric range that is generally between 10 and 20 dB and determined by the threshold and maximal comfortable loudness of electrical stimulation. After compression, the processed envelope signal is used to modulate a train of biphasic pulses. The pulse duration is set at 50 μsec/phase, and the time delay between the end of a pulse on one channel and the beginning of the next pulse on another channel is set at 200 μsec. With a four-channel processor these choices produce a rate of 833 pulses/sec on each channel. This is sufficient for high-resolution sampling of the envelope waveform.[17,18] In addition, the duration of the pulses is near the optimum in terms of power efficiency (i.e., a minimum of electrical power is required for excitation of the auditory and other peripheral nerves in the range of 50 to 100 μsec/phase).[19] The pulse delivery sequence is from apical to basal electrodes.[20]

Transcutaneous Interface

Figure 1 also illustrates passive coupling between four matched pairs of external transmitting coils and implanted receiving coils. Each pair functions as a coupling transformer, guaranteeing charge balance between the stimulus phases applied between each intracochlear electrode and the remote return electrode in the temporalis muscle. This eliminates the possibility of a net direct-current potential, which could cause neural damage and promote bone growth. Passive coils are suitable for the transmission of brief, biphasic pulses used in the CIS strategy. The four pairs of passive

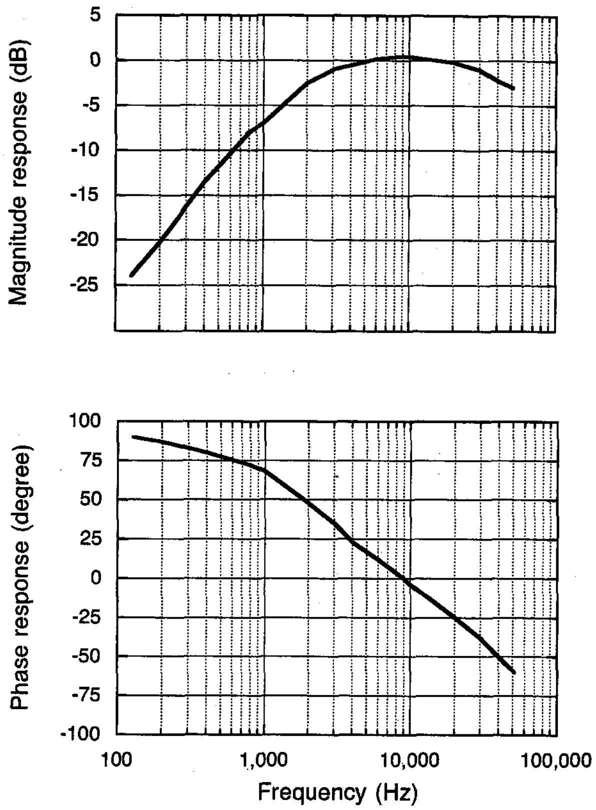


Fig. 2. Frequency response for one pair of transmitting and receiving coils. *Upper panel* shows magnitude response and *lower panel* shows phase response.

coils are similar to the House-Urban design in terms of transmission efficiency and similar to the University of California at San Francisco/Storz design in terms of assembly and geometric arrangement.[21] Ceramic magnets are used to align the external and internal coils.

Electrode Array

One end of each of the four internal coils is connected to an intracochlear electrode and the other ends of all four coils are welded together to form a single remote return electrode (not shown in Fig. 1). The coils and the electrodes may be made of the same platinum-iridium wires, in which case no junction is needed between the coil and the electrode. Alternatively, the coil may be made from less-expensive copper wire and welded to the electrode lead. In that case, both the intracochlear electrode and the ground electrode should have the same material and the same diameter, so as not to produce a "battery effect" at the junction of the different metals. Particular care would need to be taken with the insulation on the copper wires, because pinholes may permit galvanic corrosion between the copper and platinum. Relatively large electrode contacts (350 mil exposed surface diameter) can be obtained by melting a ball on the end of each preinsulated 90% platinum/10% iridium wire. With the University of California at San Francisco electrode mold and mechanical memory design,[21] the four-contact electrode array can be inserted reliably to a depth of at least 22 mm, positioning the contacts along the medial wall of the scala tympani and close to the spiral ganglion cells. Monopolar stimulation with large electrode contacts and the close proximity of the contacts to the surviving neurons should result in low electrode impedance and low electrical thresholds, reducing to a minimum the amount of power required for stimulation.

Because there are no implanted electronic components other than the four passive receiving coils, it should be possible to assemble the entire implant including the electrode array into a single injection mold as a monolithic casting of flexible silicone elastomer (i.e., hermetic sealing is not required). The absence of direct-current potentials and the absence of physical connections between coils also greatly simplify the encapsulation problem. In addition, the preset processing parameters should minimize the fitting and maintenance procedures while producing desirable open-set speech recognition in most patients.

The proposed design is not without its limitations, however. Most obviously, the physical size of the coils becomes increasingly cumbersome if extended beyond four channels. Furthermore, the coil-transformer system functions as a voltage source applied to the electrode, in contrast to the present laboratory and clinical CIS processors that use current-controlled stimulation. This voltage-controlled stimulation plus the limited bandwidth of the coil transformer will result in distortion of the biphasic square waveform. Finally, small changes in skin thickness or relative position between coils will produce fluctuations in the voltage of the stimulus pulses.

EVALUATION OF A PROTOTYPE SYSTEM

A prototype of the proposed system was constructed to evaluate its performance in tests with an experienced implant recipient. Four pairs of coils were assembled to be identical to the 3M/House coils, except for the removal of the capacitor that was used to tune the circuit at 16 kHz. The transmitting coil in each pair had 80 turns of 30-gauge copper wire and a size of 17 mm in outside diameter and 2.2 mm in thickness. The receiving coil had 670 turns of 40-gauge copper wire and a size of 15.5 mm in outside diameter and 1.8 mm in thickness. The transmitting and receiving coils were aligned by a pair of center magnets. In the following testing conditions, the four pairs of coils were arranged next to each other and formed a straight line pattern. A separation of 7 mm was introduced to simulate the separation of transmitting and receiving coils by the intervening skin in a patient. The cross-talk between two adjacent coil pairs also was measured and found to be less than 10%, or 20 dB down from the main transmission link.

Fig. 2 shows the frequency response of one of these pairs of coupled coils. The *upper panel* is the magnitude response, in which the center frequency of the coil transmission link is 9.0 kHz and the response is down 3 dB at 2.2 and 43.7 kHz. The *lower panel* is the phase response, in which the resonant frequency has a zero-degree phase. Fig. 3 shows the waveform distortion caused by the limited bandwidth of the coil transmission link. The *upper panel* is the original biphasic pulse with a pulse duration of 50 μsec/phase. The *lower panel* is the waveform at the output of the receiving coil into a 1-kΩ resistive load. Note that the output has a more rounded shape than the input, and the output has a third phase not present in the input. Both features are due to the limited bandwidth capacity of the coil system.

An implant recipient (RTI/Duke subject SR2) with more than 6 years of experience with the Ineraid device participated in the evaluation of the prototype system. This patient has high levels of speech recognition with a CIS processor.[3] He was selected in part because we wanted to measure any decrement in performance that might be produced with the prototype system, compared with a standard laboratory implementation of a CIS processor.

We note that all studies with human subjects in the RTI/Duke laboratories are approved in advance by the institutional review boards of both Duke University Medical Center and Research Triangle Institute. Each subject reads and signs an informed-consent document before his or her participation in the studies.

The standard laboratory system provided four channels of current-controlled outputs, with four independent current sources. In the prototype system the voltage inputs to the current sources were instead routed to four power amplifiers, whose outputs provided the drive signals for the four transmitting coils. The outputs of the four receiving coils were connected to the intracochlear and reference electrodes of the subject through his percutaneous connector (an integral component of the Ineraid device). The speech processors for the two conditions were identical except for the threshold and most-comfortable-loudness values used to establish the mapping functions for each channel. Thresholds and most-comfortable-loudness values were measured separately for the standard (current-controlled stimuli) and prototype (voltage-controlled) systems. The dynamic ranges

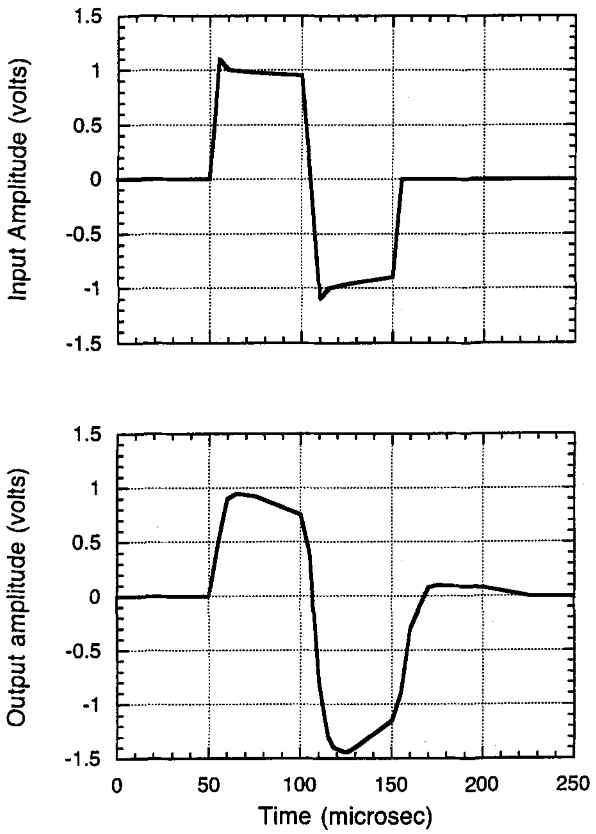


Fig. 3. Voltage waveforms for one pair of transmitting and receiving coils. *Upper panel* shows input to transmitting coil and *lower panel* shows output of receiving coil.

between measured thresholds and most-comfortable-loudness values were similar for the two conditions (for the standard system the dynamic ranges were 15.7, 20.1, 17.3, and 17.5 dB for electrodes 1 through 4, respectively; for the prototype system the dynamic ranges were 14.9, 17.9, 18.2, and 18.4 dB for the same electrodes). Both processors used 33 μsec/phase pulses, presented at the rate of 833 pulses/sec on each channel. Other identical parameters included an apex-to-base stimulation order, an attenuation of 18 dB/octave for each skirt of the bandpass filters used for each channel (i.e., sixth-order bandpass filters), a corner frequency of 200 Hz for the low-pass filters used for the envelope detectors in each channel, and an attenuation of 6 dB/octave beyond the corner frequency for those filters (i.e., first-order low-pass filters).

The comparisons included measures of consonant identification for the prototype and standard laboratory systems. In the consonant tests multiple exemplars of each of 24 consonants were presented in an /a/-consonant-/a/ context ("aba," "ada," etc.) by either a male or female speaker. The utterances were played from a

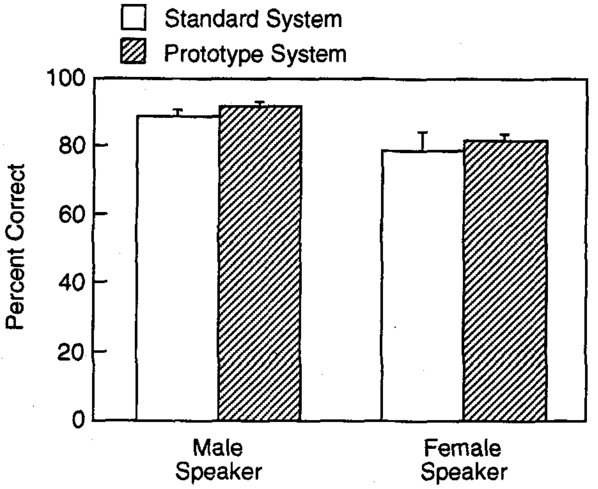
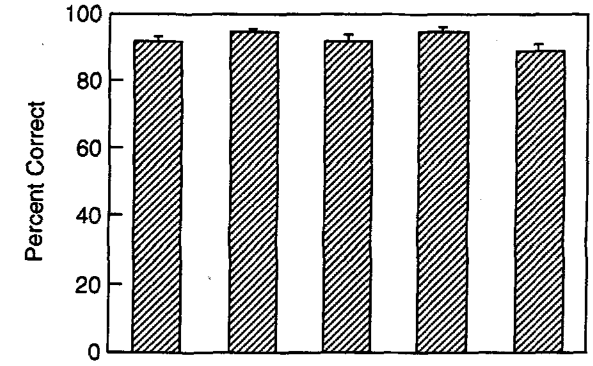


Fig. 4. Percent correct scores from 24 consonant tests conducted with subject SR2. *Bars* show standard errors of means.



Pulse dur	33	33	**16**	**16**	33
Pulse rate	833	833	833	**2525**	833
BPF order	6	6	6	6	**4**
Env order	1	**4**	1	1	1

Fig. 5. Percent correct scores from 24 consonant tests conducted with subject SR2, with male speaker only. Processor parameters include pulse duration in microseconds per phase *(Pulse dur)*, pulse rate in pulses per second *(Pulse rate)*, order of bandpass filters used for each channel *(BPF order)*, and order of low-pass filters used in the envelope detectors for each channel *(Env order)*. First processor presented is processor for prototype system, also presented in Fig. 4. Differences in values for parameters between that processor and other processors are highlighted with *boldface type*. *Bars* show standard errors of means.

video laserdisc recording[22] under computer control. A block of trials included one each of all 24 consonants. In general, 10 blocks were used for tests with the male speaker and five blocks were used for tests with the female speaker. The one exception was that 20 blocks were used for the test with the male speaker to evaluate the first variation of the prototype system, as described below. Different randomized orders were used for each block. The tests were conducted with hearing alone and without feedback as to correct or incorrect responses.

Overall percent correct scores and standard errors of the means for the comparison of the standard and prototype systems are presented in Fig. 4. The scores are not statistically different between systems for either speaker (for the male speaker $t = 1.404$, $dF = 28$, and $p = 0.17$; for the female speaker $t = 0.466$, $dF = 8$, and $p = 0.65$). This result shows that for SR2 neither current- controlled stimulation nor a particular shape of biphasic pulses is necessary for producing high levels of speech recognition. The prototype system with its coil transmission link appears to be functionally equivalent to the standard laboratory system.

We note that these consonant scores correspond to high levels of open-set speech recognition. For example, this subject correctly identified 101 of 102 key words in recorded set 3 of the City University of New York sentences with hearing alone using the prototype system.

Once the efficacy of the coil transmission link was established (at least for SR2), we decided to evaluate effects of changes in processor parameter values on performance. A principal motivation for these subsequent studies was to specify values that would support high levels of performance while minimizing power consumption and cost of manufacture.

Results of such comparisons are presented in Fig. 5. The male speaker was used for the evaluation of all processors in Fig. 5. Parameter values for each of the five processors are listed in the table at the bottom of Fig. 5. The first processor is the processor for the prototype system also presented in Fig. 4. The coil transmission link was used for all conditions.

The block percent correct scores were analyzed with a one-way analysis of variance to determine whether significant differences existed among any of the conditions. The analysis of variance was not significant ($F[4,55] = 2.388$; $p = 0.06$), indicating an equivalence of conditions for this subject and these tests. Studies with additional subjects would be required to evaluate the full generality of this result. However, our result offers encouragement that a relatively low rate of stimulation (833 pulses/sec per channel) along with relatively low orders for the bandpass (fourth order) and low-pass (first-order) filters could be used in a production device without compromising performance. Such choices would lead to reductions in power consumption and device complexity compared with the testing alternatives.

CONCLUSIONS

The clinical and social benefits of multichannel cochlear implants have been well documented. Unfortunately, these benefits currently are available only to a small part of the world's deaf population because of economic constraints. To increase the availability of cochlear implant technology to a greater share of the deaf population, it is clear that a high-performance device must be designed that can be manufactured, implanted, and maintained in developing countries. We believe that the design presented in this report would fulfill these requirements. The design includes a four-channel CIS processor, four pairs of transmitting and receiving coils, and an intracochlear array with four monopolar electrodes. All implanted components are passive and would not require hermetic sealing. With a prototype, one subject achieved excellent speech-recognition performance that was equivalent to a standard laboratory CIS processor. The cost of manufacture for the entire implant system could be quite low, especially if the manufacturing facility were in the country of device application.

The cochlear implant design presented in this article was in large part the result of enlightening discussions with our colleagues in China at the 1993 Zhengzhou conference. We are indebted to them for their insights and suggestions. We are particularly grateful for the generous hospitality provided by our hosts in China during and after the conference. We thank Franco Portillo and Chao Zhang at the House Ear Institute for their technical support in assembling and evaluating the coil transmission link, and implant subject SR2 for his enthusiastic participation in the evaluation study.

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