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Engineering Challenges in Cochlear Implants Design and Practice

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Introduction and Background

Since the first successful cochlear implantation in the early 1970's by the House group in Los Angeles, about 120,000 patients have received cochlear implants (CI) worldwide, with more every year [1]. The premise of using electrical stimulation on the sensory nerves, either for visual or acoustic perceptions, is not new. Attempts were made in the 19th century by several researchers with backgrounds in engineering and/or medicine. The only documented account for that period was one by Volta and it was an accidental observation when he applied an electrical current into his ear canals. When this current was applied, he reported he heard a bubbling or crackling sound. Many years later, the first human implant was performed by an engineer/physician team of Djourno and Eyries in 1937. Unfortunately, it was obscurely published, and at the brink of war was therefore largely neglected until the 1970's. The concept was then resurrected by the National Institutes of

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Health (NIH) with funding to support researchers in U.S. and subsequently in Australia and Europe.

In parallel with the advancement of surgical techniques, our understanding of the central auditory pathway also advanced. From a single channel design in the 70's, the industry progressed to 2 channels, and then 16 channels, and more during the late 90's. These advancements were made possible by advancement in the integrated circuits (IC) and microelectronics fabrication technologies (i.e., thanks to the "Moore's Law") that require progressively less circuit real estate, and certainly significantly lower power requirements which are crucial in any biomedical prostheses. The newer devices are also equipped with more sophisticated signal processing schemes with faster filtering on board that can process many active stimulation channels with ease.

However, from a clinical standpoint, subjective performance does not seem to linearly correlate with device engineering capabilities. There seems to be a limit of how many channels we can use, beyond which, no further speech discrimination improvement can be documented or subjectively perceived by the patients. Also, functional performance in less-than-ideal listening environments (e.g., restaurants, shopping malls, etc.) is somewhat mediocre. These limits stem from both biophysical limiting factors as well as engineering factors. The next generation of cochlear implants has to address the limiting dimension of the cochlea, the interface between the electrodes and the nerve synapses, and how the brain interprets the processed electrical stimuli. However, one thing is clear: too much information is not always beneficial, particularly if the information cannot be processed properly by the central pathway.

Synapses of Cochlear Implants

In the traditional hearing process, sound is transmitted through the outer ear as an acoustic wave. It impacts the tympanic membrane, which causes piston-like motions of the three bones in the middle ear cavity, which then vibrates a membranous structure called *oval window*. At that point, the resulting vibrations are transmitted to the fluid filled spiral chambers of the inner ear (i.e., cochlea). By the time the sound wave reaches the inner ear, reductions in the wave amplitude have occurred, as well as a wide band pass filtering process (designed to filter out irrelevant stimulation and to protect the inner ear from excessively loud stimuli). Once reaching the fluid media of the cochlea, the acoustic waves induce a traveling wave along the *basilar membrane* (*BM*) that runs along the entire length of the cochlea. The basilar membrane contains special microscopic structures called hair cells that are concentrated in a specific area called the *organ of Corti*. The hair cells sense the motion of the BM through an even smaller hair like apparatus (i.e., stereocillia and kinocilium) which are anchored to the BM. The shearing motions cause the stereocillia to open and close electrical channels along the hair cells, regulating the influx and efflux of the ions within the surrounding fluid. The opposite ends of the hair cells are connected to the receiving ends of the auditory nerves. The transmitting ends of the auditory nerves project to different portions of the brain stem and brain (e.g., cochlea nucleus, auditory cortex, etc.). When an electrical channel opens or closes at one end (e.g., the BM end) of the hair cell, a stream of chemical neurotransmitters is released into the auditory nerve fiber synapse. Once the neurotransmitter is released into the synapse a small electrical potential is elicited along the nerve body and transmitted to the brain for processing.

Along the cochlea, the BM varies in stiffness. The base of the cochlea (near the oval window) is the stiffest region, which becomes more flexible as it spirals towards the apex. This varied stiffness serves as a spectrum analyzer along the cochlea. The hair cells closer to the base are specifically tuned to high frequency spectra while the hair cells closer to the apex are tuned to low frequency spectra. Interestingly, this spectral organization remains throughout the auditory nerve complex as well as through the brain stem and brain cortices (central auditory pathway). In fact, from the moment the sound stimuli are at the point of the auricle, they will be filtered, amplitude modulated, band pass filtered, low passed filtered, and then rectified while being transduced from a mechanical

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to electrical signal. This is an extraordinary engineering and physiological feat that we try to duplicate with cochlear implants.

Thus far we have only mentioned the spectral processing of the auditory system. The reason why humans can acquire and process speech as well as other complex perceptions (e.g., music) is their ability to process sound in both spectral and temporal cues. Unfortunately, our current cochlear implants discard most temporal information. For patients whose deafness is caused by damage or complete degeneration of the hair cells, either by genetic defects, ototoxicity, trauma, or infectious processes (e.g., meningitis), and if the hair cells have been damaged for a long time, the nerve ends (not being stimulated) will start to degenerate (i.e., atrophy). Unfortunately, this degeneration is retrograde in nature (i.e., the process will also affect the development and maturity of the entire central auditory pathway as well). Fortunately, the *spiral ganglion* is rather robust and the central auditory pathway is rather plastic and the reasoning behind why we advocate for early (e.g., 12 months of age) and fast (e.g., short period of auditory deprivation) cochlear implants. Cochlear implants bypass these damaged hair cells by directly stimulating the auditory nerves within the cochlea with modulated electrical pulses.

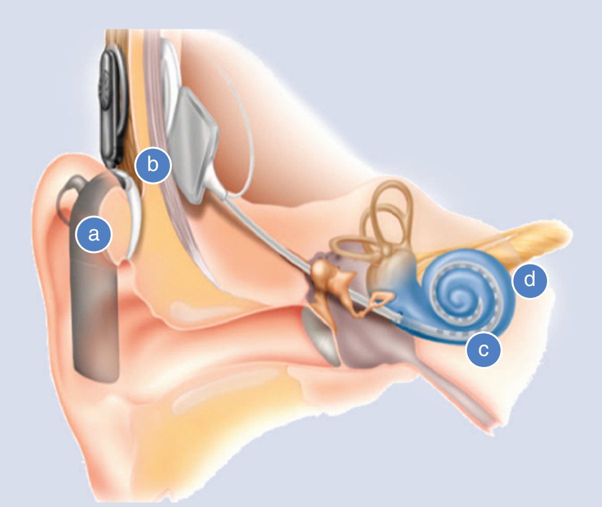

Figure 1. Graphical depiction of the cochlear implant system: (a) speech processor, (b) cochlear implant, (c) electrode array, and (d) cochlea. (Photos courtesy of Cochlear Americas, © 2009 Cochlear Americas.)

Cochlear Implant Components

Current cochlear implant systems consist of external and internal (i.e., surgically inserted) components [2]. The external component consists of a microphone, battery pack, and speech processor all housed as a single unit. The speech processor transmits auditory input via a radio frequency (RF) transmitter to an opposed internal subcutaneous receiver/stimulator. The small signals received by the receiver/stimulator are delivered to the electrodes via a biologically sealed array, which is surgically inserted into one of the chambers of the cochlea (Fig. 1). The electrodes can be arranged as bipolar, or a more commonly used, monopolar configuration. The surgical techniques are specific and are continuously evolving [1]. A picture taken during an actual cochleostomy and mastoidectomy with Nucleus Freedom insertion is shown in Fig. 2.

Electrode Array Issues

Direct stimulation of the auditory nerve is accomplished by an array of electrodes, configured as monopolar or bipolar, and is inserted along the length of the cochlea. The array is inserted surgically by drilling out the covering bone of one of the cochlea's chambers (i.e., scala tympani) near the base. The array is inserted so that the electrodes are positioned as close as possible to the spiral ganglion in an attempt to optimize the signal-to-noise ratio (SNR) and reduce impedances, which will subsequently reduce overall power requirements. Yet as individual electrodes are placed closer to each other, the interference between adjacent electrodes will increase accordingly, particularly given the ionized fluid in which they are bathed. The electrode interaction issue has limited the total number of electrodes that is possible given the total insertion depth.

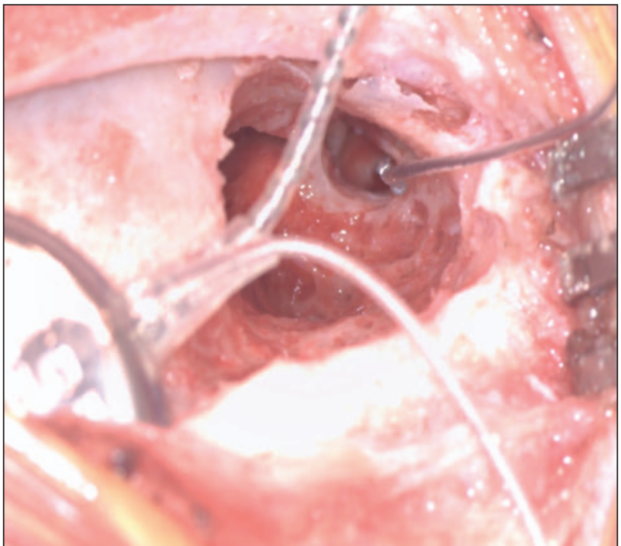

Figure 2. Actual cochleostomy and mastoidectomy with Nucleus Freedom insertion.

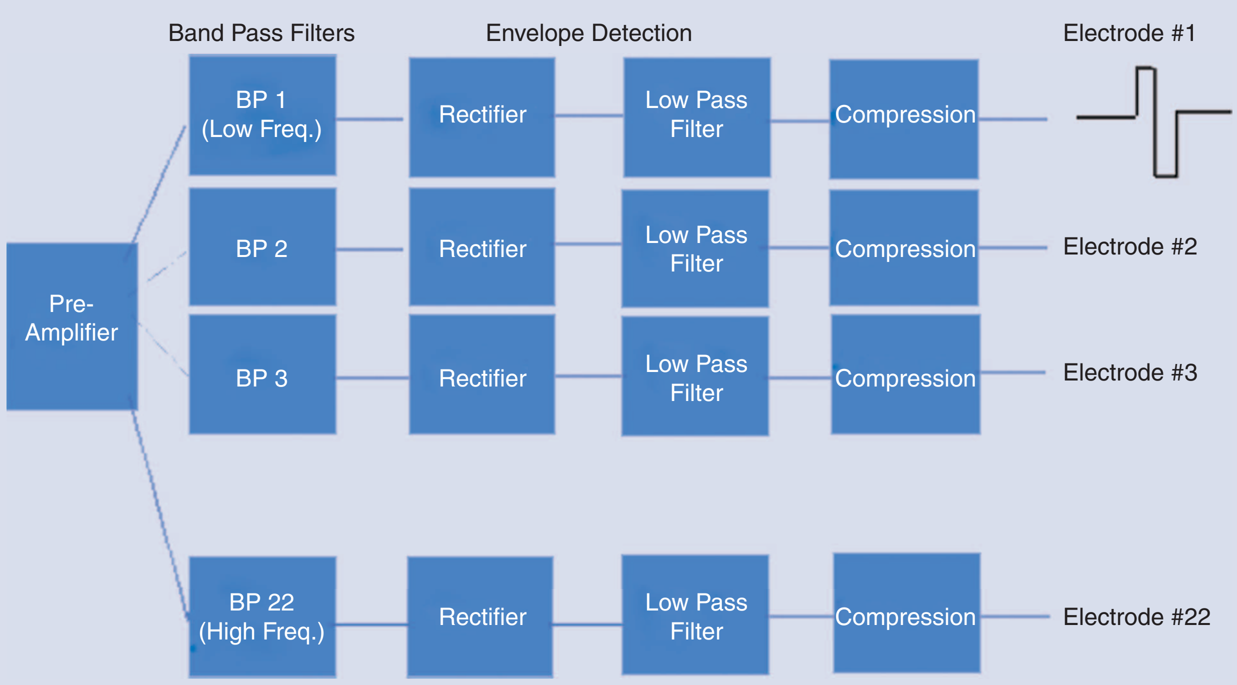

Figure 3. An example of the continuous interleaved sampling (CIS) scheme [3].

Electrode Insertion

Given the length of the array that surgeons are able to insert is approximately 30 mm and the effective length of the cochlea is about 40 mm (with the apical lumen significantly narrowing), there is a practical upper limit on the number of electrodes. This limited number of electrodes, when compared to the number of hair cells leads to a physiological conflict since there is a current maximum of 22 active electrodes and approximately 13,000 inner hair cells. This leads to a challenge of providing the patient with adequate frequency resolution with a cochlear implant since each electrode is responsible for a designated wide band of frequencies and not a precise area of excitation like the normal hair cell function. Another issue related to the electrode design and insertion is the theory of tonotopic arrangement of the basilar membrane. The basilar membrane and cochlear hair cells in a typical functioning ear is arranged in such a manner that low frequencies are associated with the apical region and the high frequencies are associated with the basal region of the basilar membrane. With ear region of the basilar membrane have an associated frequency region; it is an impossible surgical and engineering challenge to match the frequency regions of the electrode array and the basilar membrane. In addition, since the implant only goes approximately 30 mm into a 40 mm cochlea, the most apical regions of the basilar membrane will not be stimulated. As such, the low frequency auditory nerve fibers will not be stimulated.

The processing unit of a cochlear implant consists of a signal processing IC which is preprogrammed for sound processing strategies. Currently, there are three commercially available cochlear implant systems available for use in the United States: Cochlear Nucleus, Advanced Bionics Clarion, and Med EL. Although each company has its own proprietary processing strategy, they all share the same basic principles. The core processing scheme is an adaptation of a voice synthesizer developed by Bell labs for voice synthesis and recognition called continuous interleaved sampling (CIS) [2, 3]. The CIS strategy consists of compression circuitry, followed by banks of band pass filters, rectifiers (envelope detectors), low pass filters, and then the nonlinear filters which generate trains of biphasic pulses ranging from 400 to approximately 18000 pps (Fig. 3).

Engineering Aspects and Challenges of Cochlear Implant Design

As the cochlear implant design first evolved in the 70's, the design goal was to increase the number of electrodes (hence channels). This seemed, at the time, to be

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intuitive and so in a short time we progressed from one channel to three channels in early 90's, to sixteen and more by the turn of the century. This progression was made possible by exponential advancement in IC design and realization. The array of electrodes was made thinner with more electrodes packed into the approximately 30 mm of available length. The receiver/processing unit gave more signal processing power while its size stayed the same or became even smaller.

Speech Processing Strategies

Early cochlear implants (CI) incorporate the basic compressed analog (CA) processing scheme [2]. The signals received from the microphone were first gain-controlled to fit with the dynamic range (i.e., difference between threshold of response and maximal comfort levels) of the auditory nerves instead of that of the hair cells. The gain controlled signals are now fed to a bank of band-pass filters (BPFs) and then gain-controlled again before delivering to the electrodes simultaneously. The spectral and temporal information are both incorporated into the final signals. The band-pass signals have their center frequencies at 0.5 kHz, 1.0 kHz, 2 kHz, and somewhere between 3 to 4 kHz. These frequency ranges cover the speech spectrum very well. As the number of channels increase, the interference between of adjacent electrodes also increases. To alleviate this problem, current CI technology deploys biphasic current pulses delivered in a sequential manner instead of simultaneous analog signals, hence the continuous interleaved sampling (CIS) [3, 4, 5, 6, 7].

Earlier variants of CIS processing schemes were modeled after voice synthesis was designed for telephone systems in the 40's. These rather complex schemes incorporate temporal cues by detecting and incorporating information about the first and second formants (F1 and F2), in addition to the fundamental frequency (F0). However, these devices performed very poorly in reality due to their inabilities to separate the formants from environmental noise, which is relevant in evaluating a patient's function benefit. Let us not forget that voice synthesis was generated in circuitry with a significantly lower noise floor and usually of a white noise nature.

The fundamental blocks of current CIS processing strategy is illustrated in Fig. 2. Various processing schemes were developed within each block, with incremental improvements in clinical performance as all the design parameters within each block are tweaked. The initial acoustic signals extracted from the microphone have to be compressed. This is because we are bypassing the entire mechanical-electrical transduction mechanism of the middle ear/cochlea by directly stimulating the auditory nerves, which have significantly less dynamic range (up to 40 dB compared with 100 dB of normal auditory process). Various strategies are adopted for this compression stage, varying from the traditional logarithmic compression to power laws, etc. The effects of these varying schemes in our opinion are academic.

The pulse rate of the biphasic pulse somewhat correlates with the clinical performance, although there are conflicting credible reports on this issue. Common sense dictates that as the number of electrodes increase, faster pulse rate may potentially create more electric field interference, which might nullify the potential benefit of a higher pulse rate. For example, users of MED-EL devices, which have fewer electrodes hence wider inter-electrode spacing, enjoy more perceivable improvement with higher pulse rate than the Cochlear Nucleus CI, which uses more electrodes, hence narrower inter-electrode spacing.

As for band-pass filter designs, the key design parameter is how to distribute the center frequencies around the speech range, i.e., between 0.5 kHz to 8 kHz. The basic logarithmic spacing spreads the bandwidth throughout the frequency range without giving any emphasis to F1 and F2 (harmonics). Some new strategies involve devoting more bands in the F1 range (0–1 kHz) and F2 range (1–3 kHz) compared with the log spacing. These new strategies help clinical performance with vowel recognition [5, 6]. Cochlear utilizes a FFT and a Hamming window to generate its FFT bins for up to 22 channels in its Nucleus-24 device. A subset of these channels will be selected based on spectral maxima to fit the appropriate electrodes. By selecting only 8 to 12 electrodes out of the possible 22 electrodes, the pulse rate can be increased to about 2400 pps. Advanced Bionics and MED-EL alternatively

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choose to incorporate some temporal cues and support higher pulse rate by tweaking the envelope detector schemes while keeping the logarithmic filter spacing. Advanced Bionics' Clarion HiRes devices use half wave rectifiers after using band pass filters, followed by averaging windows (essentially low-pass filters with varying cutoff frequencies). The effective cutoff frequencies are adjusted based on the pulse rate, (i.e., the higher pulse rate, the higher cutoff frequencies, the smaller number of samples within one stimulation frame). The averaged signals are then again compressed to modulate the amplitudes of the biphasic pulse to match the dynamic range of the auditory nerves. The pulses are then presented at the electrodes, either simultaneously or in pairs, in a non adjacent manner, (i.e., the stimulated electrodes within a pair are a few electrodes apart; e.g., electrodes 1 and 6 in pair, then 2 and 8 in pair, etc.) to reduce electrode interaction. This strategy supports a very high pulse rate and still incorporates some temporal cues. In non-simultaneous mode (i.e., sequentially as described in the basic CIS), the pulse rate is about 2500 pps, and the averaging strategy still incorporates some temporal cues. Both modes can be selected at any time.

The MED-EL devices also use logarithmic filter spacing for their band-pass filters. The Hilbert transform is used to detect and map the envelopes of the band passed signals [8]. The Hilbert transform utilizes dither signals at different frequencies to smooth out the spectral envelopes. The MED-EL devices also have the fewest electrodes compared with other devices, and the array is significantly more flexible as well. This design allows for deeper insertion and much wider inter-electrode spacing, hence a very high pulse rate into (e.g., 50,000+).

Most of the above strategies indirectly incorporate some temporal cues into the processed speech by smoothing out the band pass filter output envelopes [9]. One way to directly enhance temporal cues is to accurately modulate the fundamental frequency (F0). Earlier attempts to modulate band pass filters input with F0 centered pulses were plagued with poor performance in the presence of noise. This is due to the fact that background noise (e.g., at restaurants) probably also has spectral maxima around F0 as well [10].

Geurts and Wouters proposed the use of two low-pass filter banks with cutoff frequencies of 400 Hz and 50 Hz, respectively [11]. The envelope depth at F0 would be enhanced by subtracting the 50 Hz log-compressed envelope from the 400 Hz log-compressed envelope. Although intuitively sound, no clinical gain in terms of pitch discrimination has been observed. Other similar spectral subtraction schemes have been derived and tested, but again no significant pitch discrimination gain has been noted.

Wilson described and validated a *current steering* concept where each individual electrode can receive different discrete biphasic pulse amplitudes simultaneously [10]. The pulse can also be delivered out of phase (i.e., reverse polarity). Three adjacent electrodes can be simultaneously excited with different amplitudes in or out of phase. This results in a step-wise summation or subtraction of the overall electric field which propagates throughout the synapses. Single adjacent electrodes can be stimulated with three current steered electrodes to reduce the overlapping electric fields interference. The current steering methodology works well with arrays that have wide enough inter-electrode spacing and is a notable departure from previously described fine structure enhancement schemes.

Since the microphone and the processor, which contain the analog and signal processing circuitry, are outside the body, researchers and manufacturers can immediately evaluate relevant clinical performance changes (e.g., incremental refinements on the analog front end to reduce power consumption, new noise reduction strategies, or new coding algorithms) are made available. This is in contrast to other types of implanted prostheses [e.g., pacemaker, implantable cardioverter defibrillator (ICD), etc.] where the receiver and electrodes array are surgically implanted and therefore cannot be modified without surgical intervention.

Noise Reduction Strategies

We briefly reviewed some of the current strategies to improve CI's performances. One of the areas that can be improved upon is performance in noise immunity. One simple strategy deploys two microphones; one is facing front, and the other rearward. This configuration is based on the fact that noise would be identically

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presented in either microphone with some time delay and hence will cancel out if one is subtracted from the other (i.e., noise cancellation). The signal (front) and noise (back) will be determined by comparing the amplitudes after compression. The resulting signal will then be differentially amplified [12]. More sophisticated schemes would involve LMS (Least-Mean-Square) filtering to minimize the spectral contribution from noise (i.e., LMSE algorithm in an adaptive filter set up).

Other noise reducing strategies, such as one proposed by Loizou, do not require multi-microphone arrangement [13]. Noise reduction can either be implemented prior to speech processing or during processing as noise spectral subtraction. Loizou proposed using a S-shaped compression scheme that dynamically changes its curvature in accordance to the estimated noise floor within each cycle [13, 14, 15].

As far as state of the art goes, it seems that we are experiencing a diminishing return in terms of functional performance as increasing the number of channels; pulse rate or processing sophistication only resulted in incremental clinical performance gain. Clinically, most of implant patients would be able to use 3 to 6 channels at any instance. No discernible objective or subjective improvement is noted as the number of channels being stimulated increases. The current coding schemes are based on our very limited understanding of how the central pathway processes sound stimuli. The current CI generation is primarily designed for speech recognition. More complex sound perceptions, such as music appreciation, remain outside of clinical standards or design parameters. Richter proposed to use fiber optic cable instead of the electrode array for stimulation of the auditory nerves [16]. This would potentially reduce channel crosstalk and power requirements as well as maximize stimulation rate and spatial specificity of excited neurons.

Within the current paradigm of CI design, there are external and internal units that are RF linked. Usually the transmitted data is encoded by variants of frame coding scheme, then embedded with error detection strategies, active electrodes assignment, and their respective amplitudes and phases. Tokens of bits are transmitted at more than 1 Mbits/second with a carrier frequency up to 50 MHz. The modulation of RF signals in CI is usually of the simple amplitude shift keying (ASK) type to accommodate for the high frequency and low power requirements. The RF power amplifier of the external unit should be high frequency, yet power efficient. The transmitting coil, and especially the receiving coil should be as small as possible, yet capable of high bandwidth. RF transmission efficiency is naturally negatively affected by thicker skin flap. Yet to minimize device extrusion, the skin flap should be at least 5 to 10 mm in thickness. Currently, about 20 mW to 40 mW are receivable at the internal coil with about 40% transmission efficiency [17].

Particular challenges arise from the internal receiver unit design. This particular unit has to accomplish several crucial tasks including decoding the transmitted data, converting them to analog signals, and all the meanwhile serving as the current sources for the electrodes. The internal unit is also charged with the tasks of monitoring electrode potentials and transmitting back to the external units (i.e., telemetry). This is required for both safety and for real-time implant programming and performance monitoring. The fundamental limitation is that high frequency transmission at any current level requires more power consumption. The high bandwidth current sources require multiple high current sources which would have to dissipate considerable heat, particularly in their ASIC packaging, posing another safety challenge aside from power consumption issues. Most modern implant systems now use multiple current sources instead of a single multiplexed current source that make the multi-electrode designs possible, yet still stay within a narrow range of safe heat dissipation. Advances in RF and analog IC integration will continue to support more efficient, safe and capable designs to accommodate more sophisticated coding strategies as they are developed. The authors are interested in pursuing the incorporation of the latest RF SoC (System-On-a-Chip) advances to bio-implants systems to achieve these common goals.

Other Advances in Cochlear Implantation

Some recent advances in clinical cochlear implant research include bilateral implantation [18] and

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round window or intramodiolar implantation where the electrodes are placed more medially or directly in contact with the modiolus [19, 20]. These initiatives are driven essentially by advances in surgical techniques. Objective performance benefits are clear for bilateral implantation, but unclear for soft techniques.

Another recent advance is an electro-acoustic hearing or hybrid CI. As the selection criteria for cochlear implants continues to become more and more relaxed, there are more patients with residual hearing who will benefit from eligibility to receive a CI. Most of these patients would still have some usable low frequency hearing. The CI systems for these patients utilize shorter electrode length to spare insertion trauma into the cochlear apex (where low frequency transduction occur). The insertion technique also requires a cochleostomy drill out to minimize lateral wall damage. Early reports of electro-acoustic hearing have confirmed distinctive performance advantages on this patient population [21]. Most CI companies either already have a hybrid CI in clinical trials or are working toward this direction.

As cochlear implant speech processor front end processes catch up to the traditional hearing aid industry, we will likely find improvements in speech understanding in a variety of listening situations. Some of these advancements include the use of directional microphone technology, noise reduction algorithms, and the digital signal processing capabilities. Through collaboration with hearing aid manufacturers, performance expectations can grow significantly when patient performance is evaluated in difficult listening environments (e.g., restaurants, concerts, etc.).

Conclusion

Among all the sensory implants developed, cochlear implants for hearing restoration are the most mature and probably have benefited the largest patient population. Other sensory implants, such as retinal implants, have adopted significant technologies and methodologies from cochlear implant advances. Cochlear implantation, like open heart surgery, has successfully challenged the old common dictum about central nerve system prosthesis, and has become one of the cornerstones of modern medicine. Moreover, the cochlear implantation paradigm is a manifestation of the integration of engineering and medicine at their best.

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Donald Y.C. Lie (S'86–M'87–SM'00) received the M.S. and Ph.D. degrees in electrical engineering (minor in applied physics) from the California Institute of Technology, Pasadena, in 1990 and 1995, respectively. He has held technical and managerial positions at companies such as Rockwell International, Silicon-Wave/RFMD, IBM, Microtune Inc., SYS Technologies, and Dynamic Research Corporation (DRC). He is currently the Keh-Shew Lu Regents Chair Professor in the Department of Electrical and Computer Engineering, Texas Tech University, Lubbock, and also an Adjunct Professor in the Department of Surgery, Texas Tech University Health Sciences Center (TTUHSC). He is instrumental in bringing in multi-million dollars research funding and also designed real-world commercial communication products sold internationally. He has been a Visiting Lecturer to the ECE Department, University of California, San Diego (UCSD) since 2002 where he taught upper-division and graduate-level classes and affiliated with UCSD's Center of Wireless Communications and co-supervised Ph.D. students. He has authored/coauthored over 130 peer-reviewed technical papers and book chapters and holds five U.S. patents. Dr. Lie has been serving on the Executive Committee of the IEEE Bipolar/BiCMOS Circuits and Technology Meeting (BCTM), IEEE SiRF, IEEE MWSCAS, IEEE TSMWCS and also serving on various TPC for IEEE RFIC Symp., IEEE VLSI-DAT, IEEE PAWR, IEEE LiSSA and IEEE DCAS committees, etc. He has received numerous awards from DRC, IBM, Rockwell, and gave numerous invited talks and short courses at IEEE conferences/workshops. He and his students have won several Best Graduate Student Paper Awards in international conferences in 1994, 1995, 2006, 2008 (twice), 2010 (twice) and 2011, and also with various prestigious scholarships. Dr. Lie is serving as the Associate Editor of *IEEE Microwave and Wireless Components Letters (MWCL)*, the Area Editor-in-Chief for the *International Journal on Wireless and Optical Communications*, and also on the Editorial Board for the i-manager's *Journal on Electrical Engineering.* He was a Guest Editor of *IEEE Journal of Solid-State Circuits* (*JSSC*) in 2009, and also is serving as a reviewer for many journals. His research interests are: (1) low-power RF/Analog integrated circuits and System-on-a-Chip (SoC) design and test; and (2) interdisciplinary research on medical electronics, biosensors and biosignal processing.

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