REVIEW ARTICLES

TECHNICAL FEATURES OF THE NUCLEUS, MED-EL AND CLARION COCHLEAR IMPLANTS

GRAEME CLARK and DAVID LAWRENCE

Department of Otolaryngology
The University of Melbourne

The performance of a cochlear implant is inextricably linked to the engineering of the device. The present paper reviews the features of several devices in regular clinical use at the present time, utilizing details from various sources.

Cochlear Implants have become an established treatment and are used by severely to profoundly deaf adults and children in almost every phase of daily life. Electronic designs have improved to meet clinical and research demands, technological developments have made the devices smaller and more reliable, and speech processing research has yielded a series of improvements in patient benefit.

The performance of a cochlear implant system is inextricably linked to the engineering of the device. It is important for clinicians to understand how various technological features can affect results. A large amount of information is available, however the rationale for the features is not always substantiated. The features referred to are for devices in regular clinical use in mid 1999: Cochlear Limited (Nucleus-24), Mel-El (Combi-40), and Advanced Bionics (Clarion-S) devices. The details are those available from the manufacturers' manuals, web sites, patents and scientific papers. These issues are discussed in more detail in the chapter on Cochlear Implants for Adults and Children in Audiological Medicine [1].

Standard speech processing strategies

(a) SPEAK:
The Nucleus system uses the Spectral Maxima Sound Processor (SPEAK) strategy which selects 6-8 spectral maxima from the outputs of 20 band-pass filters. The output voltages are presented on a place-coding basis non-simultaneously at a constant stimulus rate (250Hz) to minimise channel interactions. Fundamental frequency (F0) is conveyed by the amplitude of the stimuli. Studies by the Cooperative Research Centre for Cochlear Implant Speech and Hearing Research in Melbourne have tested variations of this strategy, including order of presentation of stimuli and the use of the fundamental frequency or random rates of stimulation.

(b) SAS:
The Clarion device uses Simultaneous Analogue Stimulation (SAS), derived from the strategy developed by the Salt Lake City [2, 3] and the University of San Francisco [4] groups and implemented respectively as the Symbion or Ineraid and the Storz or MiniMed devices. The Ineraid device presented the outputs of four fixed filters by simultaneous monopolar stimulation, while the Storz system used bipolar stimulation. SAS was subsequently used with eight filters in the Clarion processor [5].

Early cochlear implant research [6] showed that simultaneous stimulation could lead to unpredictable variations in perceived loudness due to current interaction. Loudness control under simultaneous stimulation would require an algorithm that could predict the resultant voltage fields for a number of electrodes at all intensities - this has not been achieved. The only method for avoiding channel interaction is to separate the channels temporally or spatially so that the voltage fields do not overlap. The latter may be achieved by placing an electrode array close to the spiral ganglion cells so that monopolar or bipolar stimulation can produce localised neural excitation.

Neurophysiologists in the 1940s and 1950s found that analogue stimulation of the nervous system was less suitable than pulsatile stimulation. Neurons integrate current to produce an action potential regardless of the type of stimulation, although current can be more...
precisely controlled with a pulse. A preliminary study [7] to compare analogue and pulsatile stimuli and their effects on synchrony of firing produced inconclusive results, and a more detailed evaluation [8,9] of the effects of biphasic pulses and sinusoidal current waveforms showed no significant differences in the temporal properties of the responses, although there were differences in synchrony of responses depending on pulse width and frequency.

A well-controlled comparison [10] between the Symbion/Ineraid four fixed filter system, which used analogue stimulation, and the Nucleus Multipeak-MSP system, an earlier version of the Nucleus system which extracted two formant peaks and the energy in three higher frequency bands [11], showed that there were higher mean speech scores with the Multipeak-MSP system (75%) than with the Symbion/Ineraid system (42%).

(c) CIS:
Like SPEAK, the Continuous Interleaved Sampling (CIS) strategy stimulates multiple channels non-simultaneously to reduce interactions, but at a higher rate. The outputs of six or more filters are used to stimulate a corresponding number of electrodes on a place-coding basis. Several studies [12, 13] have been performed to optimise the number of filters and stimulus rate, and a constant rate of 833 to 1111 pulses per second per channel has been recommended [5].

A comparison of the SPEAK and CIS strategies for comparable groups of patients using the six channel (electrode) SPEAK and six channel CIS strategies was first possible in 1995 and 1996. The study compared the open-set CID sentence scores for electrical stimulation alone for the CIS-Clarion system on 64 patients six months postoperatively [14] and the SPEAK-Spectra-22 system on 51 unselected patients tested between two and six months after start-up time (data presented to the FDA, January 1996). The results showed the performance for SPEAK was as good or better [15].

Maximum rates: non-simultaneous pulsatile stimulation
The manufacturers offer the CIS strategies at stimulus rates higher than 800 pulses/s. However, it is possible to electronically sample speech far more rapidly than it can be processed by the human nervous system. The auditory nerve fibres have an absolute refractory period of approximately 0.5ms, and a relative refractory period of about 2ms during which time the nerve cells cannot respond to every stimulus pulse [16]. Figure 1 shows the number of intervals between action potentials from cells in the cochlear nucleus for stimulus rates of 200, 800, 1200, and 1800 pulses/s. The duration of the relative refractory period is indicated. At 200 pulses/s the firing interval between action potentials is the same as the stimulus period (5ms) and the firing is very deterministic. At 800 pulses/s there are multiple firing periods occurring at multiples of the stimulus period, similarly to acoustic stimulation. The firing is more stochastic due to the reduced responsiveness to stimuli occurring within the relative refractory period. At a higher rate of 1200 pulses/s the interval peaks are less distinct, suggesting that at this and higher frequencies there is a progressive loss of
temporal information as the intervals between stimulus pulses become shorter than the relative refractory period and enter the absolute refractory period.

It is also possible to convey temporal information by amplitude variations at high rates of stimulation through altering the rate and population of nerves excited, although psychophysical studies [17, 18, 19] showed that only low rates of modulation (100-200 Hz) could be detected.

High rates of stimulation used within the clinically acceptable intensity levels are usually safe [20], however, the use of a high rate may damage auditory neurones at current levels and charge densities above normal clinical levels [21, 22]. In addition, the devices should be engineered to allow for charge recovery at the electrode/tissue interface between pulses. This prevents a build up of DC current which can damage nerves and cochlear tissue at levels greater than 2μA [23].

Past neurobiological safety studies have demonstrated the importance of evaluating in animal experimental studies any significantly altered rate of stimulation, as well as the electronics to be used in patients to deliver the high pulse rates. All significant changes in stimulus parameters and electrode geometry in the Nucleus system have been accompanied by animal studies. However, there are few detailed studies on safety with the use of increasingly higher stimulus rates with other systems.

Another reason for safety studies with each device is to ensure that the charge density at the electrode/tissue interface does not exceed acceptable levels. Studies have shown that charge densities below 32μC/cm² geom. per phase are safe [24, 25, 26, 27], although the upper limit for safety has not been established. The electrodes on the Nucleus array have a relatively large surface area (0.44–0.66mm²) and the pulse width used in patients can be up to 50μs but is normally 25μs. With the highest current (1.75mA) delivered through the smallest band on the Nucleus array, the maximum charge density possible is 19.9μC/cm² per phase. The surface area of the electrodes of the Mel-EI and Clarion devices are up to five times smaller (0.14mm²) than that of the Nucleus array [28, 29].

The Advanced Bionics Clarion system can produce up to 2.5mA, and at its minimum pulse width of 77μs results in a charge density of 137.5μC/cm² per phase. The pulse width can be increased, resulting in an even greater charge density. The Med-EL Combi-40 can deliver a current of 2.5mA for pulse widths between 40 and 640μs, so that the maximum charge density could range from 80 to 914μC/cm² per phase. It is important to establish the safe upper levels for charge density, particularly for the operating ranges of the Combi-40 and Clarion-S, as the maximum possible levels for these devices are well in excess of the value known to be safe (32μC/cm² per phase).

Although the benefits of high rates of stimulation have not been established, companies emphasise the importance of the maximum rates their devices can achieve. The Clarion-S is reported to produce 104,000 samples/s [29]. The term sample rate is ambiguous, and is not the same as biphasic pulse rate, but rather refers to the voltages used to represent simultaneous analogue stimulation. Furthermore, seven and not eight channels (electrodes) are used for the bipolar stimulation in SAS. Radial stimulation cannot always reach the dynamic ranges required on each electrode pair, so eight are connected longitudinally to make seven pairs. The design of the stimulator is such that 91,000 samples/s are available to stimulate seven rather than eight electrodes. For simultaneous pulsatile stimulation (SPS) two output samples are required to produce one biphasic pulse so that 45,500 pulses/s are available for distribution. Sample rate is also confusing as each of the seven electrodes can only be updated every 77μs whether this be individual voltages or biphasic pulses. In other words any of the seven electrodes can be stimulated at 12,987 samples/s or pulses/s. This will only produce quasi-stochastic responses conveying amplitude envelope information, as it is an impossibly fast rate to stimulate the nerves.

For non-simultaneous stimulation, the Clarion-S device is subject to similar limitations in information transfer as the Nucleus-24 and Combi-40/40+ systems. In this case, only one electrode is stimulated at a time. As stated for the Clarion-S, the data update interval is 77μs. This means a maximum rate of 12,987 samples or 6,494 pulses/s for distribution across eight electrodes or approximately 812 pulses/s per electrode [30].

The Combi-40 stimulates non-simultaneously at up to 12,120 pulses/s. The newer Combi-40+ can stimulate at 18,180 pulses/s [31], and when using 12 electrodes can stimulate at up to 1,515 pulses/s on each electrode. With the Nucleus-24 there is 25μs for each phase of the pulse, an inter-phase gap of 7μs for more efficient stimulation, and a shorting period of 12μs between pulses to ensure for biological safety that there is no DC build up. The resultant maximum rate of 14,400 pulses/s can be applied to one electrode or divided across electrodes giving 1,440 pulses/s on each of 10 electrodes, or 720 pulses/s on each of 20 electrodes.

**Table 1**

Comparison of technical capabilities of the Nucleus-24, Combi-40, and Clarion-S cochlear implant systems as at March 1999.

<table>
<thead>
<tr>
<th></th>
<th>NUCLEUS-24</th>
<th>COMBI-40</th>
<th>CLARION-S</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample processing</strong></td>
<td>SPIAX</td>
<td>CIS</td>
<td>CIS</td>
</tr>
<tr>
<td><strong>Maximum pulse rate:</strong></td>
<td>4.49</td>
<td>12,120</td>
<td>6,500</td>
</tr>
<tr>
<td><strong>Maximum sample rate:</strong></td>
<td>not applicable</td>
<td>not applicable</td>
<td>104,000</td>
</tr>
<tr>
<td><strong>Maximum number of stimulation channels:</strong></td>
<td>7 (SAS)</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td><strong>Mode of stimulation:</strong></td>
<td>Monopolar</td>
<td>Cochlea ground Bipolar</td>
<td>Monopolar (CIS) Bipolar (SAS)</td>
</tr>
<tr>
<td><strong>Speech recognition under investigation or proposed:</strong></td>
<td>ACE, ADRO, TESM</td>
<td>CIS+, S-PISI, SPEAK, HAP, PHS,</td>
<td></td>
</tr>
<tr>
<td><strong>Teletherapy:</strong></td>
<td>Not in regular use</td>
<td>Not in regular use</td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Implant casing:</strong></td>
<td>Titanium</td>
<td>Ceramic</td>
<td>Ceramic</td>
</tr>
</tbody>
</table>
implants. The optimal number of channels for stimulation has not been fully established. Studies [32] have shown that for the Nucleus system and the F0/F1/F2 speech processing strategy the results are progressively better for electrode numbers greater than nine. As there can be variations in the density of auditory neurones due to pathology, a further advantage for the Nucleus system in having 22 electrodes is that there are more electrodes available in areas of the cochlea where place of stimulation is more effective.

There is an interaction between mode of stimulation, electrode geometry, and cochlear anatomy for the optimal place coding of frequency. Initial research [33, 34, 35, 36] showed that bipolar and common ground stimulation would localise current to discrete groups of neurones, without it short-circuiting along the fluid compartments of the cochlea. In the bipolar mode, current passes from one active electrode to one reference electrode, while with common ground stimulation the current passes from the active electrode to each of the others in the array which have been connected together electronically to constitute a single reference electrode. It has been shown [37] that monopolar stimulation between an active and distant reference electrode may also allow localised stimulation if the electrodes are placed close to neurones.

With bipolar stimulation, if the electrodes are small or not adjacent to the spiral ganglion cells, higher current levels are required to elicit an auditory percept. The implant may not be able to deliver the current required, so the separation of active and reference electrodes will need to be increased to enlarge the area over which the spiral ganglion cells are stimulated. However, this in turn will reduce channel separation. There has been debate [38] about the merit of using a moulded array [39] to achieve placement of electrodes close to spiral ganglion cells. This array was developed to produce radial bipolar stimulation of the peripheral processes of the spiral ganglion cells and because effective stimulation is not tolerant to small variations in electrode placement [40]. A comparison of the histological effects of a free-fitting versus a moulded array [41] showed significantly more trauma for the moulded array. Other studies [42, 43, 44] have established that this trauma can lead to the loss of spiral ganglion cells. A teflon strip cutting the basilar membrane in the hearing animal can lead to a marked loss of spiral ganglion cells, as shown in Figure 2. Fractures of the osseous spiral lamina have also been shown to cause loss of spiral ganglion cells in the deafened animal [45].

The safety of using a teflon “former” to push a Nucleus free-fitting banded array close to the modiolus after insertion has recently been studied in the human temporal bone [46]. A wire former has been attached to the tip of the Combi-40+ array to force it closer to the inner spiral, and a silicone plug attached to the Clarion-S array is also being trialed. All these formers are likely to produce significant trauma as was seen in the study of Sutton et al (1980) [41].

With electrodes now-being inserted to lie close to spiral ganglion cells for improved information transfer, it is even more imperative that trauma be kept to a minimum to preserve adequate spiral ganglion cell numbers.

The Nucleus array with teflon former has been compared with a pre-curved array (without former) in a number of human temporal bones subsequently sectioned to evaluate damage [46]. In a significant proportion of insertions, the former was shown to buckle and to tear the basilar membrane and enter the scala vestibuli, as illustrated in Figure 3. For this reason, an electrode with former will not be used for advanced Nucleus systems. Sections of the human temporal bone have shown that a pre-curved array held straight before insertion is much less traumatic than an array with former [46].

Speech processing strategies under investigation

There are a number of variations to the standard speech processing strategies offered by each manufacturer which are all at different stages of evaluation.

(a) NUCLEUS-24 SYSTEM

The ACE strategy being trialed with the Nucleus-24 system is a modification of SPEAK with stimuli presented at high rates and/or with more channels. The effect of a higher rate of stimulation (in particular 800 pulses/s) with ACE has been compared with SPEAK which uses 250 pulses/s. The study [47] on a small group of subjects showed that the average results did not improve for rates higher than 250 pulses/s, however there was patient variability and so stimulus rate could be varied to suit performance.

Studies [48, 49] have shown no significant difference in consonant recognition scores with rates higher than 250 pulses/s, although there is some variability in results.
However, it was shown that manner of articulation features are better perceived using higher rates while place of articulation features are better perceived using lower rates. A speech processing strategy has been postulated, referred to as Differential Rate Sound Processor, that uses a low stimulation rate on apical electrodes, where place of articulation information is largely present, and a high stimulation rate on the basal electrodes, to better encode friction and envelope information.

Another strategy being trialed with SPEAK optimises the dynamic range for each frequency band by an adaptive mechanism, ADRO (Adaptive Dynamic Range Optimisation), and initial results indicate that it can give improved speech perception [50]. A further strategy, TESM (Transient Emphasis Spectral Maxima) [51], emphasises the transients important for intelligibility in speech and may also lead to improvements in speech perception.

(b) COMBI-40 SYSTEM

Strategies for the Combi-40 system include high rate CIS, CIS+, jitter CIS, variable rate CIS, and "n" of "m". The CIS+ strategy uses the Hilbert transform for envelope extraction. The Hilbert transform (essentially a 90° phase-shifter) is an efficient technique for detecting the speech wave envelope from each filter. The transform was first described early in the 20th century and has been in regular use in communication engineering since the 1970s [52]. Jitter CIS means the addition of a random rather than a constant stimulus rate. This is also available with the SPEAK strategy, and for some subjects it is reported to make the sound more natural. The "n" of "m" strategy selects "n" stimulus channels from "m" filter outputs. This is the principle underlying all the Nucleus speech processing strategies (FOIF2, FOIF1/FOIF2, MULTIPEAK, and SPEAK). SPEAK has been shown to be the optimum "n" of "m" strategy [53].

(c) CLARION SYSTEM

Clarion offers the possibility of simultaneous analogue as well as pulsatile stimuli through SPS (simultaneous pulsatile sampler). The issues relating to simultaneous stimulation are discussed above. Partial simultaneous strategies are HAP (hybrid analog pulsatile processor), QPS (quadruple pulsatile sampler), and PPS (paired pulsatile sampler).

HAP would use simultaneous analogue stimulation for the lower frequencies, and non-simultaneous pulsatile stimulation in the higher frequencies. This type of strategy was initially described by von Wallenberg et al. (1990) [54], who presented the results for a 4-channel system in which a broad band analogue signal was presented on the most apical electrode, and the second formant as pulsatile stimuli to one of the three more basal electrodes. Vowel identification was significantly better for the hybrid compared to the single-channel system. Furthermore, a hybrid speech processor has been developed in the Human Communication Research Centre, Melbourne [55]. This strategy encoded voicing information on a separate apical electrode, and constant rate spectral maxima information on the other electrodes.

A comparison [56] with a standard spectral maxima processor showed no difference in the scores for the hybrid scheme presenting suprasegmental information on a separate electrode. Another version of the hybrid strategy has been developed at the Cooperative Research Centre for Cochlear Implant Speech and Hearing Research in Melbourne. This uses single-channel stimulation on an apical electrode to provide temporal information for excitation of residual low frequency hearing electrophonically, and electrical stimulation of the auditory nerves for high frequency spectral information [57].

The PPS and QPS are systems for stimulating either two or four electrodes simultaneously with a CIS strategy. The electrodes are selected so that they are at a distance from each other to reduce interactions from overlapping electrical fields.

Behind-the-ear speech processor

Many patients find a behind-the-ear speech processor desirable, particularly as it is more convenient and cosmetically pleasing to dispense with the leads passing from the microphone to the body-worn device. Miniaturisation of the processor requires high powered Zinc-Air batteries and a low power consumption, which is easier to achieve with strategies using low stimulus rates. The Nucleus behind-the-ear speech processor, ESPr, has been in use since January 1998 with the SPEAK strategy. An initial behind-the-ear speech processor has been used by a patient using a Med-El device, but it is was not in regular clinical use in 1999. Advanced Bionics have proposed a behind-the-ear speech processor for 2000.

Telemetry

Telemetry allows information, such as voltages from electrodes on the array generated while delivering a stimulus pulse, to be transmitted to the external programming system. Pathological changes can be assessed by using telemetry information to determine the tissue impedance around the array. The Nucleus system can also measure the compound action potential (CAP) in the auditory nerve which can help determine stimulus thresholds and dynamic ranges. The CAP can be measured more rapidly than the EABR procedure which is made using surface electrodes, and a child does not require an anaesthetic. The Nucleus 24 system can also determine whether the electrode voltage has exceeded the voltage compliance, and hence that a programming change is required.

Reliability

Reliability is an important issue for the prospective patient. Uniform procedures and meaningful reporting are essential for the clinician. It takes time to accumulate meaningful statistics on the overall reliability of the different products, and short-term estimates for new models can be very misleading. The past history is important as reliability depends on accumulated manufacturing experience. Specific information is also needed on the incidence of package failures, sealing leaks.

AUST. J. OTOLARYNG. JANUARY 2000, 3, No. 5
cracks to the case, fractures of the electrodes or transmitting coil, and electronic failures. For children, in particular, it is important that the implant is resistant to blows to the head. Implant design should evolve to the point where all sporting activities are not contra-indicated.

The commonly accepted method of reporting the reliability of implanted medical devices is to report the percentage of the population surviving a number of years. The cumulative survival percentage then includes all units that remain clinically functional. All units that fail either mechanically or electronically and so require replacement to restore function are counted as device failures in this calculation.

It is to be expected that manufacturers will make design changes to improve reliability. As an example, by strengthening the implant design the reliability (at 12 months) of the Nucleus 24M for all modes of failure was improved from 99.7% to 99.8% for adults and from 98.6% to 99.7% for children. Reliability data have been reported in the literature by Cochlear Limited, but at this point in time not to the same extent by the other manufacturers.

Acknowledgments

We wish to thank Dr. Hochmair from Med-EI; Mr. A. Mann from Advanced Bionics; and Mr. J. Patrick from Cochlear Limited for information.

References

(Submitted).
Hochmair, personal communication.

Clark, G. and Lawrence, D.
