A Multiple-Electrode Hearing Prosthesis for Cochlear Implantation in Deaf Patients

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Abstract. A multiple-electrode hearing prosthesis for cochlear implantation in deaf patients has been developed at the University of Melbourne. It has been designed as a multiple-electrode implant to provide the best chance of enabling patients to understand speech. It has been shown that an electrode array can be threaded along the coils of the inner ear close to residual auditory nerves. Experimental studies have indicated that the long-term implantation of the array will not lead to significant degeneration of auditory nerve fibres. Loss of platinum from the stimulating electrodes can be minimized with a biphasic constant current pulse, where the first phase is negative with respect to ground. The receiver-stimulator component has also been designed to provide 10 - 15 channels of stimulation. Furthermore, the phase and amplitude of the stimuli to individual electrodes can be varied to enable the localization of the electrical fields to discrete groups of nerve fibres, and the correct method of frequency and intensity coding to be determined. Finally, the device should be used in the first instance for a specially selected group of adults who are post-lingually deaf.

Key words: Multiple-Electrode - Cochlear - Implant - Prosthesis.

I. Medical and Biological Aspects

1. Introduction

It has been estimated [7] that about one in every two hundred persons has a total hearing handicap and could benefit from a prosthesis to help restore hearing. A multiple-electrode hearing prosthesis implanted into the mastoid and cochlea offers the possibility of restoring some hearing, and enables the patient to understand speech. It should only be used in patients with very severe or total hearing loss, in whom there is a reasonable expectation that there are sufficient residual auditory nerves to enable electrical stimulation to be detected by the higher brain centres. It should be designed so that the normal physiological mechanisms used to code frequency and intensity information are approximated, particularly in patients who have previously experienced hearing. Furthermore, it should permit speech to be preprocessed and presented to the electrode array as a pattern of electrical stimuli that maximizes speech perception. The biological and medical aspects of research that has led to the development of the receiving and stimulating component of a multiple-electrode hearing prosthesis by the University of Melbourne Department of Otolaryngology and Electrical Engineering (UMDOLEE) are discussed in this section.

1.2 Anatomy of the Cochlea

A photomicrograph of the cochlea or inner ear of the cat is shown in Figure 1. As with the human, it consists of a fluid-filled canal which makes about 2 3/4 spirals around a central column of bone called the modiolus. The turns are subdivided into basal, middle, and apical ones. The basal turn has an opening called the oval window which receives one of the small bones of the middle ear called the stapes so that sound vibrations in the air can be transmitted to the fluid in the inner ear. There is also another opening into the basal turn called the round window which is covered with a membrane that moves outward as the bone in the oval window moves inwards. This allows movement of the inner ear fluid. From the photomicrograph in Figure 1 it can be seen that the turns of the cochlea are further subdivided by
two membranes into three partitions. The top one is the scala vestibuli, the middle one the scala media, and the bottom one the scala tympani. The stapes bone in the oval window is in contact with the fluid in the scala vestibuli, and the membrane over the round window is in contact with the fluid in the scala tympani. The fluid in both these canals is in communication through a small opening at the apex called the helicotrema. The scala media is, however, a separate closed space containing a fluid called endolymph which has a different ionic composition from the perilymph in the other scalae.

The organ of Corti or sense organ of hearing lies in the basilar membrane in the scala media. The hair cells in the organ of Corti respond to mechanical vibrations which are converted to electrical voltages called microphonics. Sounds of high frequency produce a maximum displacement of the basilar membrane in the basal turn, and the frequency of best response is reduced progressively toward the apical turn. The terminal auditory nerve fibres make contact with the hair cells and are excited in temporospatial patterns appropriate for the acoustic stimulus. This information is then conveyed along the nerve fibre to a ganglion in the modiolus, and then along the auditory nerve to higher brain centres for final coding.

1.3 Surgical Approaches

Before a multiple-electrode hearing prosthesis could be developed, it was necessary to determine whether an array of electrodes could be implanted in close proximity to the terminal auditory nerve fibres which normally convey speech information. Initially, Simmons [50] implanted an array close to auditory nerve fibres in the modiolus. Although this method had the advantage of allowing low threshold currents to be used, the location of the array could not be predicted with any certainty. Subsequently, Michelson [40] used an array inserted into the basal turn through the round window, but this could not be made to negotiate the middle and apical turns to reach the areas of the cochlea which are important in speech perception. Pialoux and Chouard [46] have implanted electrodes by drilling a number of openings into the bony cochlea. This method has the disadvantages that cranial surgery is required. Each opening drilled into the cochlea further increases the risk of damage to residual auditory nerve fibres. As all these approaches lead to difficulties in placing electrodes close to the auditory nerve fibres which convey speech information, it was considered necessary to develop an alternative approach. It has been found possible to implant electrodes close to these nerve fibres [12] by drilling a single opening in the apical turn and threading the electrode bundle along the scala tympani towards the basal turn (Fig. 2). This is the procedure used with the hearing prosthesis described. The main inherent dis-
advantage is that it can be difficult to isolate the electrical field around each electrode.

1.4 Histopathological Findings

If an electrode array is to be implanted in the inner ear, it is important that it should not lead to the degeneration of the auditory nerve fibres that it is hoped to stimulate electrically. Initially it was shown [51] that electrodes could be inserted into the basal turn of the cat's cochlea through the round window without permanent loss of function, providing infection did not occur. Subsequently, it was demonstrated that electrodes could be inserted directly into the cochlea by drilling on opening in the overlying bone [14] without significant loss of auditory nerve fibres, again providing infection did not occur. In this study repeated electrical stimulation was also carried out suggesting that electrical stimulation per se is not a factor leading to loss of auditory nerve fibres. A more recent animal experimental study [10], in which the operations were carried out aseptically and the electrode array threaded along the scala tympani through an opening drilled in the apical turn, has demonstrated that the operation can be performed without significant loss of auditory nerve fibres for periods in excess of one year, except at a point underlying the opening drilled in the bony cochlea. With regard to the length of time required to assess auditory nerve degeneration, it has been shown [53] that following trauma to the cochlea, spiral ganglion cell and auditory nerve fibre loss occurs for a period of 20 weeks, but thereafter the loss is minimal.

1.5 Electrode Arrays

To stimulate discrete regions in the cochlea, it has been necessary to develop an array of 10 - 15 electrodes that can be passed along the scala tympani. The electrodes in this array should be of an inert metal such as platinum, and be insulated with a material which has no tissue toxicity such as Teflon. The bundle should have an overall diameter less than 0.7 mm, as the smallest dimension in the narrowest part of the apical turn is 0.7 mm.

Furthermore, it should have the appropriate mechanical properties [12] which will enable it to be inserted along the length of the cochlea. Two types of arrays meeting these specifications have been realized. First, in the Department of Otolaryngology, a technique has been developed to specially strand Teflon coated platinum wire. Second, thin film technology and radio-frequency sputtering first used to produce a platinum array [52] have been further refined [30] to achieve an electrode array appropriate for inserting around the turns of the cochlea through an opening drilled over the apical turn [11].

1.6 Electrode Physicochemistry

An understanding of electrode physicochemistry is important as long-term stimulation at high-current densities can lead to electrolysis with the production of toxic substances and the loss of metal from the electrode. During normal operation it is hoped that the current will be passed through auditory nerve fibres as a result of double-layer charging at the electrode-tissue interface. However, due to constraints on the electrode size and the need to provide a range of intensities for speech perception, current density levels may be achieved which lead to electrolysis. Therefore, attention has been given to ways of reducing this effect. It has been found, for example, that not only is electrolysis reduced with a bi-phasic wave, but is further reduced [6] if the first phase is negative with respect to ground (phase lag) rather than positive (phase lead).

This study was carried out on platinum black electrodes. It has been shown [49], however, that platinum black electrodes can lose part of their platinum during mechanical insertion and deteriorate in biological fluids, probably due to the entry of protein molecules into the porous surface. For this reason we consider that smooth platinum rather than platinum black electrodes should be used with cochlear implants. A study on smooth platinum [3] has confirmed that electrolysis and metal loss are less with a phase lag rather than a phase lead bi-phasic stimulus wave.

Consequently, this stimulus configuration has been incorporated into the design of the UMDOLEE hearing prosthesis. Furthermore, it has been necessary to determine the amount of platinum loss with a phase-lag waveform at the maximum current densities required so that the lives of the specially stranded and thin-film-sputtered arrays can be predicted. Using a sensitive spectrophotometric technique for detecting platinum, it has shown [3] that with a continuous 1 kHz stimulus at a current density of 2 mA/mm² the platinum loss was 20 ng/m/day. Consequently, when used continually with a maximum current density for an average of 10 h/day, the multiple-stranded wire would have a life of about 90 years before 50% of the metal would be lost. In the case of the thin-film sputtered array it would be about ten years. This means that either type of array can be used the thin-film array, although it has a restricted life, can be withdrawn and another one inserted as it is smooth and atraumatic. On the other hand, the specially stranded wire bundle needs to have a longer life because it cannot be withdrawn without causing considerable tissue damage due to the resistance created by the coils of wire around the outside of the bundle.
1.7 Neural Excitability

In the design of the UMDOLEE prosthesis, consideration has been given to the electrical stimulus parameters that are important for neural excitation. First, it is the current flowing through the tissue rather than the voltage across the electrodes that generates an action potential, and since the electrode impedance varies with current amplitude and may fluctuate unpredictably with time, a current source is necessary. Second, a stimulus current range from 0-1 mA has been selected, because behavioural studies on cats [15] with electrodes placed in the scala tympani showed that their stimulus thresholds to electrical stimulation were well within this range. Third, a behavioural study on cats [15] and a strength-duration curve measurement in an acute cat experiment [17], shown in Figure 3, indicate that pulse widths from 0.1 to 1.0 ms do not lead to greatly increased stimulus thresholds. In fact the chronaxie of the strength duration curve in the cat (Fig. 3) was 0.18 ms, indicating that a greater current is required to reach threshold for stimulus pulses with duration less than 0.18 ms. From these findings it has been considered appropriate to use biphasic current pulses with a width of 0.18 ms per pulse.

1.8 Frequency Coding

It is important that a hearing prosthesis convey an adequate amount of frequency information for speech perception. It is preferable that the frequency information be coded along normal physiological lines, especially in patients who have previously experienced hearing (postlingually deaf), as their brains will be more receptive to information coded this way.

There have been two main theories of frequency coding. According to the first or volley theory [54], we detect the frequency of the sound on the basis of the rate of stimulation, or more specifically the period between nerve action potentials. This is illustrated in Figure 4. At low rates of stimulation, the action potentials occur at a constant phase of the sound wave. At high rates of stimulation the refractory period of the nerve prevents an action potential occurring every stimulus cycle; nevertheless, more recent studies [47] have shown that the nerve fibres will fire in phase every second, third, or fourth cycle, with the result that a population of nerves can fire in phase with the sound wave to levels in excess of 5.0 kHz, even though the individual fibres cannot do so. Acute experimental [8] and behavioural studies [13, 59] on cats, however, have shown that with electrical stimulation the neural and behavioural responses on a rate basis are much more restricted than with sound. These studies indicate that a single-channel hearing prosthesis is unlikely to convey all the frequency information required for speech comprehension. This has been confirmed by clinical studies on patients who have received a single-channel cochlear implant [32, 40].

The place theory is the other main theory of frequency coding, which states that frequency is detected on the basis of the place or site of excitation within the cochlea and brain nuclei, as illustrated in Figure 5. There
is now increasing evidence that this theory is more important than the volley theory in frequency coding [24, 25]. This means that if a hearing prosthesis is going to lead to satisfactory speech perception, it must be a multiple-electrode system. Furthermore, studies on frequency selectivity [60] indicate that the harmonics in complex sounds cannot be resolved if they produce maximal excitation within a critical band. This means that electrical stimulation need only be restricted to the region of the critical band, which is equivalent to a distance of 1.2 mm along the cochlea. As the main aim of the hearing prosthesis is to enable speech to be understood, electrical stimulation can be further restricted to the critical bands in the frequency region essential for speech perception (150 - 3,000 Hz). On this basis there is a need for 15 electrodes. In addition, intelligibility studies on speech which has been passed through a number of bandpass filters, indicate that a minimum of 10 channels is required [25]. Consequently, the hearing prosthesis has been designed with the capacity to provide 10 or 15 channels of electrical stimulation.

To achieve a restriction of the stimulus current from each electrode to a group of nerve fibres within a critical band, it would appear that there may be some difficulties. For example, electroanatomical and physiological studies [2, 34, 35, 39, 43] have shown that the scala tympani is a low-resistance electrical pathway, and this will increase the spread of the electrical field along the cochlea. The spread of the electrical field along the scala tympani is expressed quantitatively as the length constant, which is the distance along the scala over which the electrical voltage is reduced by 1/e or approximately 9 dB. Alternatively, it may be expressed as the voltage drop in dB/mm. A study [2] has shown the voltage drop to be about 6 dB/mm, although there is some evidence [43] that it is greater in the basal rather than the apical turn.

One possible way of reducing the spread of the electrical field along the cochlea is to fill the scala tympani with a material which has a high resistance. This has been carried out with two surgical approaches for the implantation of cochlear electrodes. First [41], an electrode array has been embedded in silastic, and fitted tightly into the basal turn of the cochlea; second [46], electrodes have been placed directly into the cochlea through a number of holes drilled into the overlying bone, and the area isolated by filling the cochlea with silastic.

There are problems, however, with these mechanical methods for isolating the electrical field. In particular, introducing a large electrode array into the basal turn may fracture the spiral lamina and lead to the loss of auditory nerve fibres, while attempts to isolate compartments in the cochlear turns with silastic can also lead to cochlear trauma and to the loss of the auditory nerve fibres it is hoped to stimulate. This is emphasised by an histopathological study [10] which has shown that these nerve fibres are sensitive to trauma and are lost in areas underlying holes drilled in the cochlea.

It is considered preferable to achieve isolation of the electrical field by other means. One possible way [55] is to produce a sharpening of the field by varying the phases of the pulses to the electrodes on either side of the central one, as illustrated in Figure 6. This possibility has been confirmed in a physiological study on experimental animals [4]. A behavioural study [42] has also demonstrated that there was a difference in a cat's response to simultaneous electrical stimulation of neighbouring electrodes, depending on their phase relations. The UMDOLEE hearing prosthesis has a limited capacity to vary the phase relations of the electrical stimuli to different electrodes and is being further modified to improve this capacity in the light of the positive physiological findings discussed.

Another way of restricting the current field is to take advantage of the limited dynamic range [25] of the auditory nerve fibres to electrical stimulation, which is about 6 dB from threshold to saturation. If the stimulus level at one electrode is kept within the range, it should not result in the excitation of nerve fibres underlying a neighbouring electrode 1.2 mm away, as the electrical field attenuates at the rate of 6 dB/mm. At this rate of attenuation, the current level would be below the threshold for the nerve fibres in a neighbouring critical band. To achieve isolation in this basis it is, however, necessary that the hearing prosthesis has the capacity for the stimulus levels to be varied independently to the different electrodes, and that the difference between individual stimuli should be less than 6 dB. These design requirements have been incorporated into the UMDOLEE hearing prosthesis [27].

Although it is important to design a hearing prosthesis to code frequency on a place basis and to restrict the current flow to one critical band, there is evidence...
from physiological and psychoacoustic [24, 25] studies that the place theory is not adequate in accounting for frequency perception over a wide dynamic range of intensities. For example, the auditory nerve fibres have been shown to have a dynamic range of 20 - 50 dB for sound [24], yet psychoacoustic studies have shown that frequency resolution is maintained over at least a 100 dB range. It is now thought that the fine time structure of the nerve action potentials may be important in coding frequency over an extended intensity range [25]. For this reason, the UMDOLEE prosthesis has been designed so that the timing of the stimulus pulse can be independently controlled for each electrode. The timing sequence for a single electrode is shown in Figure 7. It can be seen that with each time frame the stimulus pulse can commence at one of eight points in time. The timing sequence is described in more detail in Section II of this paper.

1.9 Intensity Coding

Although the perception of intensity change is not of great importance in understanding speech, large variations can affect speech discrimination [1]. Therefore, the coding of intensity also needs to be considered in the design of a hearing prosthesis.

There have been two main theories of intensity coding. The first states that intensity is coded on the basis of the mean rate at which nerve fibres discharge. There are, however, difficulties with this theory, as studies [24, 25] have shown that all the auditory nerve fibres at a certain frequency have similar thresholds and a dynamic range for intensity from 20 - 50 dB. Therefore, the normal dynamic range of 120 dB cannot be coded on this basis alone.

On the other hand, the second theory states that intensity coding occurs on the basis of the total population of nerve fibres stimulated. A more intense sound would result in a travelling wave along the basilar membrane which has a greater amplitude and wider spread of membrane displacement, and this would lead to the excitation of a greater number of auditory nerve fibres. Again, this theory does not explain all the facts. A psychoacoustic study [56] has shown that with band-stop noise, as illustrated in Figure 8, the subject can discriminate the whole intensity range, even though the white noise has masked all but a small area of the cochlea. This limited the spread of the travelling wave and the excitation of greater numbers of nerve fibres with an increased intensity.

Due to the limitation of both of these theories it would appear that the fine time structure of nerve firing may be of importance in achieving a normal intensity range. From physiological studies [26] it would appear that the extended intensity range may be achieved by an interaction at the dorsal cochlear nucleus level between inputs from more than one channel. This would again emphasize the need for independent control of the pattern of stimulation to individual electrodes. This is a feature of the UMDOLEE hearing prosthesis.

1.10 Patient Selection

As the implantation of a hearing prosthesis is an experimental procedure, it is considered important that studies only be carried out on carefully selected patients. The details of the criteria adopted by the Department of Otolaryngology at the University of Melbourne have been outlined elsewhere [16]. Certain points should, however, be emphasized. The procedure should be carried out in accordance with the guidelines for doctors involved in clinical research as outlined in the Declaration of Helsinki [18].

We consider that initially only patients who have previously had hearing (post-lingually deaf) should be operated on, as their brains should have been programmed to code sound on known physiological lines. This provides a reference for assessing the results of electrical stimulations. Furthermore, as the patients have heard previously, they are in a position to compare the
sensations produced by both electrical stimulation and sound. Although the procedure should ultimately be of benefit to children with total hearing loss, it should not be used in this age group until the long-term effects and results are better known.

It is anticipated that a long and involved postoperative rehabilitation period will be needed to obtain maximum benefit; therefore, patients selected for this procedure must be prepared to attend the centre regularly for a long period of time. Patients need to have total or near total hearing loss as shown on a pure tone audiogram, and they should be tested with speech audiometry in order to better assess their hearing handicap. It should be ascertained they have had an adequate trial with a modern hearing aid. They need to have a series of psychological tests to assess their suitability for the procedure on more general grounds. Only after these and other procedures have been carried out should the patient be considered for the cochlear implantation of the multiple-electrode hearing prosthesis.

II. System Design Aspects

In this section we describe the design and realization of the implantable multichannel hearing prosthesis referred to in Part I. The development of this device has relied particularly on technological advances in the areas of environmental packaging and microelectronics. Current microelectronic circuit techniques have been used to produce a complex electronic device which is small enough to be fitted into the limited space available and which, despite its complexity, has a low power consumption to minimize tissue heating. This device is packaged using materials which ensure that the implant is biologically inert and that the electronics are protected against the hostile in vivo environment.

2.1 The Design Specification

2.1.1 General Design Philosophy. Multichannel electrical stimulation of the cochlear nerve endings can be accomplished in two ways: the first requires a percutaneous electrical connection between an implanted electrode array and the stimulation circuitry [44, 50], while the second approach involves the transfer of stimulus information transcutaneously via an indirect coupling [19, 23, 31, 40]. The former technique offers obvious advantages from the stimulation hardware viewpoint, but incurs the possible risk of post-operative infection, patient trauma, and long-term patient irritation. The latter approach eliminates these disadvantages but introduces the technical problems associated with, first, transferring multichannel information across a tissue barrier, and second, packaging the implanted electronics unit in materials which ensure that it is both biologically inert and protected in vivo.

In the single-channel hearing prostheses developed by Djouno and Eyries [19], Michelson [40], and House [31], a simple transcutaneous inductive coupling technique was employed, the output of which drove the implanted electrode directly. Using the same technique, Brindley [5] has developed a multichannel system for stimulation of the visual cortex. This system involved eighty independent inductive links and required extensive surgery. An alternative multichannel approach is to use a single data link and to multiplex the stimulus data [20, 29, 57]. This method requires implanted electronic circuitry to decode and to demultiplex the transcutaneous data. Furthermore, power must be provided to operate the implant circuitry [48]. Dobelle et al. [20] have proposed a multichannel system for both visual and auditory cortex stimulation using a single-radio-frequency link for both data and power. White [57] has proposed using a transtympanic optical link for multichannel time-multiplex data transfer with a separate inductive link for powering the implanted device. This results in a low-efficiency, but wideband link for high data-rate transfer, and a high-efficiency narrow band link for power transfer. Gheewala et al. [29] have developed a similar dual-link transfer system utilizing ultrasonic data transmission to control a four-channel hearing prosthesis. Thus a number of workable options exist for the transcutaneous transfer of both power and multichannel data.

For this design, a dual-link transfer system was chosen utilizing independent inductive links for both the power and data transfer. This system is capable of high-transfer efficiency for the power link and requires simple and therefore reliable detection circuitry for the data link. The use of an independent transcutaneous power link not only obviates the need for an implantable power source, but also ensures that the implant can be rendered inoperative should a failure of the implant electronics occur.

Furthermore, the availability of several excellent biocompatible materials and techniques for packaging and protection [21, 22], together with experience from long-term implantation of cardiac pacemakers [58] and biotelemetry systems [28, 37], indicates that it is technically possible to develop a reliable biocompatible implant incorporating relatively complex electronic circuitry.

The package is to be implanted in a cavity in the mastoid bone [9], located behind the external ear, as this location allows easy access to the cochlea for the electrode connection and was considered satisfactory.
both cosmetically and from a patient comfort viewpoint. There will, however, be severe restrictions on the maximum size of the implant package, a conservative estimate for the package being 3 cm x 3 cm x 0.5 cm [38].

Finally, the array of stimulating electrodes will be either a wire bundle or thin-film array as described in Section I. Since the wire bundle array cannot be withdrawn from the cochlea without causing considerable tissue damage, it is essential that this array be detachable from the electronics package to permit replacement of that unit if necessary. A compact hermetically sealed connector which can connect the stimulus electronics to either the wire-bundle array or thin-film array has thus been developed as part of the electronics package [45].

2.1.2 Functional Specifications. From Section I it was concluded that between ten and fifteen channels would be adequate for stimulation of the speech frequency segment of the cochlea. Consequently, the system design was sufficiently flexible to permit ten- or fifteen-channel operation without basic design changes being required.

The stimulation waveform was specified in accordance with the data presented in Section I, a biphasic current pulse with the leading phase being negative and with each phase period being fixed at approximately 180 μs.

Two stimulation parameters were chosen: the amplitude of the stimulus current which was designated the intensity control and the instant of stimulation of any channel relative to an external time reference which was designated the phase control. For the control of both these parameters, a digital rather than analog system was chosen, with the data being transferred transcutaneously as a serial-time multiplex-bit sequence. This results in a high-reliability data processing system with high noise immunity and minimal sensitivity to circuit component variations. Furthermore, digital control of the parameter, which involves accurate timing, minimizes the complexity of the decoding circuitry required. As a consequence, however, control over both phase and intensity parameters will be of a discrete rather than continuous nature. The specific resolution of each parameter was based on an evaluation of current neurophysiological research consistent with minimizing the complexity of the implanted electronic circuitry.

The intensity control allows independent variation of the stimulus current of each channel from a minimum of approximately 70 μA to a maximum of approximately 1 mA in fifteen 70 μA steps. This arrangement satisfies the requirements noted in Section I and provides less than, or equal to, 6 dB increments in intensity for levels above 70 μA.

The stimulus time format consists of basic 1 ms intervals or frames, which are equal to the period of the external time reference. During each frame, control information for each channel is transferred to the receiver-stimulator. Each frame is subdivided into eight 125 μs phase periods: the stimulation cycle may be initiated at the start of any phase period, except that any channel can be stimulated only once during any frame. Thus the maximum steady-state frequency of stimulation for each channel is 1 kHz. The phase control parameter will allow variation in the temporal pattern of firing of different neural populations excited by the field of each electrode, as discussed in Section I. Furthermore, by varying both the intensity and phase controls so that overlap of the negative and positive phases of adjacent electrodes occurs in the time domain, a limited degree of field sharpening can be achieved. Finally, with eight possible stimulation times in each frame, any channel may be stimulated at a steady-state frequency, f, corresponding to the series

$$f = \frac{1}{1 + 0.125n} \text{kHz where } n = 0, 1, 2, 3, \ldots \ldots$$

2.2 System Operation and Design

2.2.1 General Design Outline. Figure 9 depicts a block diagram form the overall structure of the prosthesis. It comprises three basic components, viz: the speech processor, the transmitter, and the receiver-stimulator [27].

The purpose of the speech processor is to analyze the input of each waveform and from this generate up to fifteen digitally encoded data channels. Initially this component will be realized using a computer, so that various strategies of speech processing may be investigated. The details of the speech processing programs to be used are beyond the scope of this paper.

The transmitter unit interfaces the computer data to a time multiplexer and generates a serial data stream which is then transferred transcutaneously to the implant. In addition, the transmitter transfers power to the implant.

The receiver-stimulator, which is implanted, demodulates, decodes, and digitally demultiplexes the serial data stream. This demultiplexed data initiates and controls the stimulation of the electrodes by means of up to fifteen independent digital-to-analog conversion (DAC) and output stages.

2.2.2 The Transmitter and Transcutaneous Links. Figure 10 shows a block diagram of the transmitter. The stimulus data corresponding to the fifteen possible channels is presented to the transmitter line receivers by the computer in the form of eight sixteen-bit words loaded
Fig. 9. Block diagram of the overall structure of the prosthesis

Fig. 10. Block diagram of the transmitter

Fig. 11. Timing diagram of a segment of the transmitted serial data train showing the relative phase between the bit clock and data bits. The synchronizing word contains one bit delayed in time relative to the bit clock. Detection of this bit in the receiver-stimulator maintains correct frame synchronization.

The carrier frequencies used by the two transcutaneous links were 112 kHz for the power link and 10.752 MHz for the data link at the frame rate of 1 kHz. Each word, with the exception of the last, contains data for two channels plus two check bits. The last word contains data for one channel only. If the data received is invalid, the line receivers are disabled, preventing erroneous data transfer to the implant. The eight data words are converted to serial format and stored in a data buffer until required by the serial train generator. The loading of the data words can be performed in approximately 50 μs. The remaining 950 μs prior to the next data transfer are required by the computer to ensure that continuous transfer of data from auxiliary mass storage units to the transmitter can be maintained.

The clock and control unit generates all timing and control information for the data loading, multiplexing, and power/data transmission. All clocks are derived from a stable 3.584 MHz crystal oscillator. The output of the data buffer comprises groups of seven-bit words, corresponding with each channel, which are loaded in parallel into the data mode select and serial train generator. After loading, each word is clocked out serially by a 112 kHz-bit clock to modulate finally the data transmitter stage, the output of which is a pulse-modulated high-frequency carrier signal. The serial train generator may alternatively be loaded with preset data to enable testing of system hardware.

The output serial data train, a typical segment of which is shown in Figure 11, comprises the fifteen seven-bit words corresponding to the fifteen possible channels. Following the fifteenth word is a frame-synchronizing word, which has a duration equal to that of a channel word. The data bits are time-synchronized to the bit clock as in Figure 11.

Three of the data bits in any word in a frame are phase control bits (Fig. 11). These determine when stimulation is to be initiated for the corresponding channel during the following frame period. Figure 12 summarizes the operation of the phase control facility, showing the possible stimulation times and stimulation period for one channel during a frame-synchronizing period. The remaining four bits in each word are intensity control bits and determine the stimulus level for that channel during the next frame period.

The carrier frequencies used by the two transcutaneous links were 112 kHz for the power link and 10.752 MHz for the data link.
Fig. 12. Timing diagram of the stimulus time format showing the phase periods and possible stimulation times for one channel relative to the frame synchronization period. The horizontal bars represent the duration of the stimulation for the particular value of the three phase bits indicated. The dark intervals in each bar allow the output current to return to zero at the completion of each phase. A typical output current waveform for the phase bit value: 101 is shown. Note the finite slope at each current transition.

MHz for the data link. The choice of carrier frequency was determined by: (i) functional circuit requirements, (ii) tissue power absorption at high frequencies [33], and (iii) minimization of crosstalk between the links.

The links were realised using two pairs of coils whose design was such that the coupling efficiency, misalignment tolerance (both axial and lateral), and minimization from interference both from external radiation and by self-radiation were optimized. The coils were constructed in the form of a flat disc or pancake configuration [36], with the data coil being placed concentrically and coplanar with the power coil for compactness.

The 112 kHz power link was designed to maximize the transfer efficiency power levels up to 500 mW with 4 mm of time between the transmitter and receiver coils. An overall power convertor efficiency of greater than 60% was achieved [27]. At a carrier frequency of 112 kHz and coil spacings of the order of 1 cm, or less, it is reasonable to ignore the contribution of tissue power absorption to the overall efficiency, this loss being less than the estimated loss of 0.44 at 400 kHz [22].

2.2.3 The Receiver-Stimulator. A block diagram of the receiver-stimulator unit is given in Figure 13. Both the power and data link signals are received by tuned circuits to minimize interference from external radio frequency sources. Two supply rails (+7.5 V and -7.5 V) with respect to the implant reference ground are derived from the 112 kHz power link using bridge rectification and series pass regulation. These voltage levels also represent the two logic levels used in the digital circuitry, minimizing the number of common bus lines. The bit clock is also derived from the unrectified power signal input. The two reference levels required by the biphasic current output generators are derived from the supply rails. The pulsed-radio-frequency-data signal is demodulated using an active detector. The data train and bit clock are inputs to the clock generation and data-forming stage. The outputs of this stage are a common clock bus comprising the five clock and control lines necessary for timing control of the channel control stages and the serial data train. The control channel stages perform the dual functions of digitally demultiplexing the serial data train and decoding this data so that independent control over
the phase and intensity parameters may be effected for each channel. The serial data is clocked through the channel control stages in synchrony with the bit clock, and is stored at the end of the frame period. This information is used to control the stimulus initiated during the following frame period. The three phase bits for each channel preset a binary counter which is incremented by a clock with a period of 125 μs equal to the phase period. When the counter reaches a predetermined number, the stimulation cycle is initiated and the four intensity bits are gated through to the corresponding DAC and output stage for the particular channel. This stage performs a digital-to-analog conversion on the intensity data: the resultant voltage then drives a voltage-controlled biphasic current source.

A typical output waveform is shown in Figure 12 for the phase bit data: 101. It should be noted that there is a period of 62.5 μs following each phase of the stimulus which allows the output current to return to zero. Without these intervals, the effects of bandwidth limitations of the particular analog circuitry employed in this stage would produce asymmetries in the current waveform and a corresponding charge imbalance. When an electrode is not stimulated, it is electrically isolated from the preceding circuitry. This also ensures that excessive stimulation can be prevented for a particular channel should a fault develop in the corresponding analog circuitry.

2.3 Realization of the Implantable Receiver-Stimulator Unit

2.3.1 Outline Description. The implantable electronics unit has been realized using a combination of CMOS and multiple-funktion analog-integrated circuits, interconnected using thick-film hybrid technology. The choice of device technologies was made in order to minimize overall power dissipation of the implant. The dimensions of the volume available for the implant electronics were such that a number of hybrid substrates had to be stacked vertically. Two different hybrid electronics units were developed: a power supply and control decoder, and a five-channel stimulator. The power supply substrate can be connected to one, two or three stimulator substrates to produce a five-, ten-, or fifteen-channel electronics unit. The initial prototype is a ten-channel unit, using the three hybrids shown in Figure 14. The two similar substrates contain identical circuitry, the difference in size being a requirement of the technique used for substrate interconnection as described below.

The hybrid circuitry is contained in a single hermetically sealed metal container which has a number of glass seals through which electrical connections are made to the receiver coils and the electrode connector. These components are in turn enclosed, together with the electronics unit, in a second hermetically sealed enclosure.

2.3.2 The Hybrid Circuitry. The power supply and control substrate contain the power supply circuitry, the data demodulator, data formatting and receiver clock generator described in Section 2.1. All components are standard, commercially available, small-scale integrated circuit CMOS or discrete devices. All inputs to this circuitry including the power supply lines are protected against external interference and transients which might otherwise cause irreversible damage to the CMOS devices.

The stimulator substrates each contain the channel control and stimulation output circuitry for five channels. The complexity of the channel control circuitry together with reliability considerations prompted the use of a custom CMOS process to combine the functions of eleven small-scale integrated circuit CMOS devices into a

![Fig. 14. The three substrates of the receiver-stimulator. From left to right: upper stimulator substrate, lower stimulator substrate, power supply substrate. Scale: 1 division = 1 cm](image)
single medium-scale-integrated circuit device. Component density and tolerance requirements also dictated the use of thin-film resistor arrays, rather than thick-film resistors. Components cover almost 30% of the total substrate area of the smaller stimulator substrate.

2.3.3 Packaging. A cross section of the ten-channel stimulator is shown in Figure 15. The stimulator substrates are stacked above the power supply, connections being made between substrates with duplicate wire bonds. This is a simple and reliable method of substrate interconnection but requires substrates of different widths as can be seen in Figure 15. The substrate stack is sealed inside a gold-plated Kovar container, through which connections are made to the coil assembly mounted above the container, with the electrode connector mounted beside it. The power coil is backed by a ferrite plate which both maximizes the efficiency of the power transfer and minimizes heating of the container due to eddy currents.

The connector incorporates a pair of substrates onto which conductor patterns have been printed and a section of layered elastomate material, comprising alternate layers of conducting and nonconducting elastomate have been printed. The elastomate is compressed between the substrates, thus electrically connecting matching sections to the conductor patterns.

The receiver coils and connector materials are protected by being enclosed, together with the hermetically sealed electronics package, in a second hermetically sealed enclosure (Fig. 16). This consists of a conformal gold layer 1 μm thick, which encloses the entire unit with the exception of the connector seal. This seal consists of a polytetrafluoroethylene (PTFE) gasket and medical-grade stainless-steel pressure plate. The gold layer is thick enough to be impermeable but thin enough to have negligible effect on the inductively coupled power and data links.

Finally, the gold layer is coated in a conformal layer of medical grade silastic. The overall result is a package with the only materials making direct contact with the tissue being silastic, stainless steel, or PTFE. All these materials have been shown to be biologically compatible.

1A patent application has been lodged for this connector and the device. Please address enquiries to Mr. R. Marginson, Vice-Principal, University of Melbourne, Parkville, 3052, Australia.
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References

3. Black, R.: Corrosion of platinum electrodes in biological fluid. (submitted for publication)
18. Declaration of Helsinki. World Medical Assembly (1964)
27. Forster, I.C., Patrick, J.F.: An implantable externally powered multi-channel hearing prosthesis. (submitted for publication)
45. Patrick, J.F.: The encapsulation of hybrid circuits for surgical implantation. (submitted for publication)
51. Simmons, F.B.: Permanent intra-cochlear electrodes in cats, tissue tolerance and cochlear microphonics. Laryngoscope 77, 171 - 186 (1967)
55. Thornton, A.R.D. (personal communication)

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