1 Introduction

Many neurological disorders are caused by the absence of neural impulses or their failure to reach their natural destinations in otherwise functional systems. For example, strokes and spinal cord injuries usually leave the peripheral nerves and muscles intact but deprive the patient of the ability to activate them voluntarily. Conversely, the loss of or damage to peripheral sense organs can result in abnormal sensations or no sensation at all but leaves intact those areas of the brain that normally process such information. Over the past 25 years, the biophysical processes and biomaterials required to activate neurons electrically have become sufficiently understood to make feasible the design of functional electrical stimulators (FES) that can be used chronically for some clinical disorders. (For recent reviews, see Agnew and McCaigery (1990).) However, the engineering effort required to develop a multichannel stimulator for a particular application remains prohibitive for all but the largest organisations working on the most common disabilities. The microstimulator described here is the first of what we hope will be a family of modular devices that can be configured easily and inexpensively to provide custom multichannel systems for neural control in clinical and experimental applications.

1.1 Intended clinical applications

For many clinical applications of functional electrical stimulation, achieving an adequate degree of control requires the electrodes to be implanted in the immediate vicinity of the target nerves and muscles, as opposed to fixed to the skin surface. Historically, three strategies have been employed:

(i) Percutaneous wire electrodes: Much important research has been done with fine, flexible wires inserted through the skin into underlying muscles (Peckham et al., 1988). However, such leads have a steady attrition rate due to flexion fatigue (Kicher et al., 1984–87), they are subject to mechanical trauma and infection and they are unlikely to be cosmetically acceptable for general clinical use.

(ii) Multichannel implanted stimulators: Several multichannel stimulators have been designed for neuromuscular applications (Smith et al., 1987; Keith et al., 1989; Strownik et al., 1979; Troyk and Poyezdala, 1987; Meadows et al., 1987) and there are on-going efforts to adapt multichannel stimulators originally designed for pain control and cochlear prostheses. However, designing, implanting and maintaining systems of cables and connectors from the large, centrally implanted stimulator package to the multitude of distant potential target sites presents formidable systems design problems.
(iii) Single channel implanted stimulators: There have been a few attempts to build miniaturised stimulators that can be located at or near their individual targets (Vodovnik et al., 1971; Hildebrandt and Meyer-Waarden, 1984). However, to date, these devices have been relatively large, poorly controlled, inefficiently powered and difficult to combine into large multi-channel systems.

The device described in the present paper is a single-channel implanted stimulator that is intended to combine the flexibility of percutaneous implantation with the precise control and reliability of hermetically encapsulated, digital circuitry.

1.2 Specifications

The following specifications are an extension of those originally generated by the Neural Prosthesis Project of the National Institute of Neurological Disorders and Stroke, US National Institutes of Health.

(a) Implant device size: 2 mm diameter, 10 mm length
(b) Packaging: hermetic, inert, biocompatible under passive and active pulsing conditions
(c) Power: on-line inductive coupling from external control unit
(d) External coil size: 9 cm diameter, either flat or elongated over 20 cm length
(e) Physical range: anywhere within the elongated coil or up to 5 cm out of the plane of the flat coil
(f) Number of independently addressable devices: 256
(g) Maximum pulse repetition rate: 50 pulse s⁻¹ per device
(h) Pulse width control: 0-256 µs in 1 µs steps
(i) Pulse amplitude control: 0-1 to 15 mA in two ranges of 15 linear steps each
(j) Basic pulse waveform: monophasic square with capacitive coupling for charge balancing between pulses
(k) Commandable waveform options: recharge current can be limited to 10 or 100 µA; end of stimulus pulse may be a square or exponential tail of 300 µs (as suggested by Fang and Mortimer (1991) for anodal block in nerve cuffs).

2 Design

2.1 Electrodes and power storage

The extremely small size of the implanted device and relatively long distance to the large external coil limits power transmission to that attainable in an air-core transformer with an extremely low coupling coefficient between primary and secondary coils (probably less than 0.03). On the other hand, the maximum duty cycle is only about 1.3 per cent (one 256 µs pulse every 20 ms). This suggests a design in which power is stored capacitively between pulses. However, the small package offers little space for a conventional discrete capacitor chip capable of storing the 3.84 µC implicit in a 15 mA stimulus pulse with a 256 µs duration. Furthermore, this charge must be stored at a voltage sufficient to overcome the output impedance of the two electrodes and the intervening tissues of the body.

We are using sintered, anodised tantalum as a ‘capacitor-electrode’ with respect to the body fluids (Guyton and Hambrecht, 1974). This simultaneously solves several design problems in a single component with well-documented biocompatibility:

(i) The porous tantalum provides a large interfacial surface with the tissue, resulting in a low output impedance and thereby reducing the compliance voltage required for output current regulation.
(ii) The same large surface generates a large capacitance for power storage; typically 5-15 µF.
(iii) Anodised tantalum has a very low DC leakage level when biased up to 80 per cent of the anodisation voltage (Guyton and Hambrecht, 1974) and tends to self-heal in body fluids (Rose et al., 1985).
(iv) The capacitor electrode eliminates the possibility of net direct current flow even if the control electronics fail.

The other pole of the stimulator must then be polarised cathodically with respect to the tantalum. We have elected to use iridium, which can be electrochemically activated using cyclic voltammetry (Robblee et al., 1983). The activation builds up an electrically conductive layer of iridium hydrous oxide that is capable of being cycled reversibly between the +3 and +4 valence states, thereby transforming electron motion in the underlying metal into ion fluxes in the surrounding solution without inducing irreversible electrolysis of the water or metal (Pickup and Buss, 1988). The interfacial impedance tends to be very low, particularly near neutral polarisation, further reducing the necessary compliance voltage.

2.2 Mechanical structure

Fig. 1 shows the current package design based on experience to date with the various components and semi-automated assembly techniques under development. The components are described below in approximate order of assembly:

(a) Tantalum electrode assembly: Powdered Ta metal is moulded and sintered into a pellet on the end of a 0-25 mm diameter Ta stem (supplied by AVX Tantalum Corp., Biddeford, Maine). After anodising, a pre-formed glass washer (N51A soda-lime glass, supplied by Friedrich and Dimmock, Millville, NJ) is melted onto the Ta stem using a microtorch and the protruding stem is gold plated and resistance welded to a shim plate.

(b) Iridium electrode: A 0-25 mm diameter iridium wire is melted in an acetylene microtorch to form a 1-5 mm diameter ball at one end and cold-formed to provide a small flat for wire-bonding at the other end.

(c) IC chip: A custom integrated silicon chip, 1-4 mm square and 0-37 mm thick with aluminium pads for conventional gold-wire ball-bonding, was used. We have selected a double-poly P-well CMOS (3 µm) process so that the substrate is at the V+ supply rail to which the Ta is connected.

(d) Ferrite winding-core: A low conductivity, high permeability nickel-zinc ferrite stock (µ = 800) is ground into two half-cylinder shapes, each with a longitudinal groove and stepped shelf on its flat face. The bottom ferrite core has a metallised pad on the flat side of this shelf, on which the IC chip and Ta assembly are mounted with silver-filled conductive epoxy. The Ir electrode is epoxied into the groove and connected to the IC chip by a flying wire bond. The top ferrite core is epoxied over the bottom ferrite core. It carries two metallised pads on the outer, curved surface of the shelf, which are divided by a solder-stop strip into four connection pads.
Coil winding: Insulated copper wire (approximately 25 μm in diameter) is wound in two layers totalling about 400 turns on the ferrite core. The copper wire is soldered to the two larger pads and flying wire bonds connect the two smaller pads to the IC chip; these are protected with junction-coat.

Glass capsule: The completed electronic assembly is slid into a precut length of glass capillary tubing (N51A, 2 mm OD x 1.7 mm ID). Microtorches seal the tubing to the glass bead on the Ta stem and to the back surface of the Ir ball. The Ir must be electrochemically activated after this heating, which is accomplished by touching its surface with an Ir whisker in the phosphate-buffered saline solution.

2.3 Power transmission

Details of the class E driver used to obtain efficient power transmission from the external controller to the implanted microstimulator are described elsewhere (Troyk and Schwann, in the press). Briefly, the problem consists of several parts:

(i) The carrier must provide power, data and clocking pulses for many implanted devices. We have chosen 2 MHz because it lies between the AM and FM radio bands, it is simply divided into the 1 μs clock necessary for pulse width control, it can be handled relatively efficiently by CMOS circuitry and it is possible to design a self-resonant receiver coil with sufficient Q within the confines of the package dimensions.

(ii) The low coupling coefficient requires very high current (several A) in the primary coil. This can be achieved with reasonable power dissipation only if the primary coil and the driver circuit act as a nearly perfectly reactive load. The problem is further complicated by unpredictable deformations and the proximity to conductive surfaces of the primary coil, which must be worn by the patient like an article of clothing. These problems have been solved by a novel driver circuit that self-tunes to the critical operating frequency at which current can be injected into the primary coil.
only when the voltage and the voltage-slope across the switch in the driver are both zero.

(iii) The highly ballasted resonance of the class E driver tends to compete with the need to modulate the carrier to encode data for transmission. This problem has been solved by synchronous frequency modulation over a very narrow range (approximately 0.1 per cent), which produces relatively large amplitude modulation (approximately 20 per cent) in the primary coil current within a few carrier cycles. Such modulations are easily detected by a circuit in the receiver circuitry which compares short-term fluctuations in the mean voltage of the receiver coil with a longer term mean voltage. Manchester encoding ensures reception of both carrier levels at least every two bit-times.

To ensure reliable operation, the circuitry is designed to present an almost constant load to the receiver coil. The voltage available from the rectified carrier (modest overvoltage protection) is regulated to a limit at one of two selectable current-limited rates. The digital logic operates from a regulated -2 VDC derived from the unregulated supply (VL in Fig. 2).

2.4 Stimulus control

While they are quiescent, all implanted devices receive a steady pattern of alternating 0 and 1 bits and listen for a string of five 0 bits signifying the beginning of a device command. This is followed by a three 8-bit control words (Fig. 3):

(a) Address word: A microstimulator is activated only when this word matches the address in its read-only-memory.
(b) Pulse width: Data loaded into a digital comparator terminate the stimulus pulse after the specified number of 1 MHz clock cycles.
(c) Waveform control: Four bits are required for stimulus current amplitude, one bit for current range (1-5 or 15 mA maximum nominal), one bit for stimulus termination (square or exponential), one bit for interstimulus recharging current (10 or 100 μA) and one bit for data parity.

3 Test results

3.1 Electrode characterisation and pulse tests

Both the Ta and Ir electrodes can be modelled as frequency-dependent capacitive interfaces in series with the access resistance of the surrounding body fluids. For electrodes with dimensions similar to those shown in Fig. 1, the total impedance in normal saline solution at the relevant frequencies (10–30 kHz) was about 60 Ω for Ta and 75 Ω for Ir. The resistivity of the muscle and connective tissue that would be expected to surround an implanted stimulator might increase the total load impedance to 300–500 Ω. Thus, a 7-5 V compliance would be sufficient to drive the maximum current of 15 mA.

Ta electrodes anodised to +15 V DC had a 10 μF capacitance and could be operated at +10 V DC bias with only 13 nA of leakage current. This provides a total charge storage capacity of 100 μC, resulting in negligible rundown of compliance voltage during the maximum pulse of 3.84 μC.

Ir electrodes activated by cycling for 20–30 min at 0.5 V s⁻¹ had charge storage capacities of about 1000 μC, consistent with their estimated surface area of 0.076 cm².

Pairs of Ta and Ir electrodes were subjected to continuous trains of stimulus pulses and recharging currents while monitoring their potentials against standard calomel reference electrodes (Fig. 4). For steady-state conditions, they behaved as expected from their impedance characterisations.

Fig. 5 demonstrates an important feature of the Ta-Ir configuration for non-steady-state conditions. During the initial start-up and during any significant change in duty cycle, the total polarisation of the system changes, reflecting the ability of the recharging circuit to keep up with the demands for stimulus current. Virtually all of this polarisation appears across the Ta, whereas the Ir always floats back to a slightly negative polarisation against

![Diagram](image-url)

**Fig. 3** Data encoding scheme for one stimulus command to one stimulator (see text for details). Each transmission requires 288 μs, so 69 separate devices could be activated in sequence at the maximum rate of 50 pulses s⁻¹ for each device.
Fig. 4 Breadboard testing of electrode configuration at low stimulus rate (left column) and near maximum ratings (right column). At low rates, the Ta remains polarised to nearly the potential of the charging power supply of +9 VDC (measured with respect to standard calomel electrode (SCE) (top)) and the recharging current is barely discernible after the pulse (bottom). At high rates, the Ta polarisation drops to a lower level (+3.6 V between pulses); this is still sufficient to drive the full 10 mA during the stimulus pulse, but the recharging current starts to approach the 72 pA available through the current-limiting recharge resistor. The potential excursions of the Ir electrode remain within ±0.4 V for both cases.

Fig. 5 Iridium potential against calomel reference electrode during various pulse trains. Changing the stimulus duty cycle (new conditions shown at arrows) results in a new polarisation level in the Ta-Ir electrode system. After a few seconds, all of the change appears in the Ta, with the Ir floating consistently to a slightly negative potential between pulses.

calomel. This is important for two reasons: First, the resistivity of the iridium hydroxide layer is nonlinearly voltage dependent, and rises rapidly if the material becomes strongly reduced by negative (cathodic) polarisation. Secondly, the safe charge-carrying capacity of the electrode depends on the available voltage excursion before it approaches the working potentials for electrolysis (approximately ±0.8 V). In our Ta-Ir system, even the largest pulses specified always produced Ir potential excursions that were well within the desired potential window.

The phenomena in Fig. 5 do bring to light two important considerations:

(i) Each time a microstimulator is powered up, the recharging current will flow steadily until the large Ta capacitor is polarised to the available compliance voltage. The 100 pA recharging current, necessary to keep the system operating steadily at its maximum stimulus level, might generate undesirable neural excitation, particularly if the device were positioned in a sensitive location where only low current or brief stimulus pulses were to be used. Therefore, the default condition is the 100 pA recharging option; a similar current flows to discharge the electrodes when the power carrier is removed.

(ii) During operation, it is desirable to avoid fluctuations in total electrode polarisation that might be caused by
either stimulus loading or movement between the primary and secondary coils. This is avoided by using a current-regulated recharge circuit (in place of the current-limiting resistor used in these tests) and a cut-out circuit which prevents stimuli from being delivered if the V - supply falls below the total electrode polarisation (i.e. the IC is drawing power from the electrodes).

3.2. Package hermeticity

A number of minor problems had to be overcome to obtain glass-to-metal seals that passed the helium leak test to the detection limit of $1 \times 10^{-10} \text{cm}^3 \text{s}^{-1} \text{atmosphere}^{-1}$. In principle, it should be relatively easy to achieve a completely hermetic glass-to-metal seal for the small, round profiles of the Ta and Ir electrode stems. As desired, the N51A glass provides a similar coefficient of thermal expansion $(5.5 \times 10^{-6})$ to both the Ta $(6.5 \times 10^{-6})$ and the Ir $(6.0 \times 10^{-6})$. Both metals form stable surface oxides which are readily wet by molten glass. However, the drawing process for making wire from these highly refractory metals tends to leave linear scratches and furrows that may result in slow, steady leaks.

In the case of the Ir, SEM studies revealed quite deep linear voids, probably associated with intercrystalline grain boundaries. This problem was overcome by forming the glass seal to the back of the remelted Ir ball, which presented a very smooth surface.

In the case of the Ta, the cleaning and anodisation seem to leave a smooth, nonporous oxide surface that produces hermetic seals to glass. However, Ta metal is so readily oxidised in air that a porous structure such as the sintered electrode will ignite and burn if it comes in contact with the microtorch flame. This problem has been overcome by holding the Ta electrode in a closely fitting metal fixture, taking care that it does not provide such a good heat sink that the stem does not reach the melting temperature of the glass. The fixture itself must be made of solid Ta metal. Otherwise, foreign metallic particles may scratch and become embedded in the Ta electrode surface, where they interfere with complete anodisation, producing DC leakage.

It should be noted that very small devices, such as the microstimulator, pose an unusual problem for hermeticity testing. Large leaks may escape detection following the usual helium bombing procedure because the helium inside the device leaks out before the test measurement can be made. Such leaks are best detected by soaking the finished devices in dye solutions and rejecting those parts that exhibit streams of bubbles or internal dye droplets. Fine leaks just below the detection limit of even the most sensitive helium sensors still pose a serious problem, because water vapour leaking at undetectable rates will saturate the tiny internal air space in only a few weeks of immersion. Short of 100 per cent life testing, the only assurance is to rely on sealing techniques that, in principle, should have zero leakage rates—hence our concern about slow leaks around longitudinal scratches in the electrode stems. It should be noted that the modular nature of the microstimulator combined with the intrinsic DC-blocking capacitance of the Ta electrode makes the consequences of an occasional device failure much less severe than for a central, multichannel stimulator package.

4 Further work planned

At the time of writing this paper, all of the components except the custom IC have been procured and tested successfully for electrical and mechanical properties, including incorporation into breadboard circuitry. The IC design has been completed and is undergoing PSPICE simulation prior to sending to the foundry. Control and exercising software and a PC-based test station are under development. It is expected that completed prototype devices will be available for bench and animal testing in the second half of 1991.

Acknowledgment—This work has been supported by contract N01-NS-9-2327 of the US National Institutes of Health, the Canadian Network of Centers of Excellence for Neural Regeneration and Functional Recovery, and by the Alfred E. Mann Foundation for Scientific Research.

References


Authors' biographies

Gerald E. Loeb was born in New Brunswick, New Jersey in 1948. He received the BA and MD degrees from Johns Hopkins University, Baltimore, MD, in 1969 and 1972, respectively. After completing a surgical internship at the University of Arizona, he was a research neurophysiologist and Section Chief at the National Institutes of Health in the Laboratory of Neural Control, NINCDS, from 1973 to 1987. Since 1988, he has been Professor of Physiology and Director of Special Projects in the Bio-Medical Engineering Unit of Queen's University, Canada. He is Chairman of the Biomedical Engineering Committee of the Canadian Medical Research Council.

Jean Zamin was born in 1950 in Kingston, Ontario, and received her B.Sc. (Hons.) degree in Physics from Trent University in 1972 and her M.Sc. in Physics from McMaster University in 1976. She worked in materials characterisation at the Xerox Research Centre, Mississauga, from 1976–79 and then at the Alcan Research Centre, Kingston, from 1979–83 as Co-ordinator of Electron Optics. After five years at home and as a part-time teaching assistant in Physics at the Royal Military College, she joined the Biomedical research team at Queen’s from 1988–90. She is presently in St Charles, Illinois, with her family.

Joseph H. Schulman received his B.S. in Applied Physics, 1960, and his Ph.D. in Zoology, 1969, with specialisations in Spectroscopy, Genetics, and Neurophysiology from UCLA. In 1969, he was technical founder of Pacesetter Systems. For the last 22 years, he has been Chief Scientist and Vice President of research and development. He has been directly involved in the development of the rechargeable cardiac pacemaker, the first use of two-way telemetry in cardiac pacemakers, and many other devices. Today, he is at the Pacesetter campus in Sylmar directing the Cochlear Stimulator, Microstimulator, Functional Electrical Stimulation program, and other advanced research projects.

Philip R. Troyk received the BS degree in Electrical Engineering from the University of Illinois, Urbana, in 1974, and the M.S. and Ph.D. degrees in Bioengineering from the University of Illinois, Chicago, in 1980 and 1983, respectively. He is currently an Assistant Professor in the Pritzker Institute of Medical Engineering, Illinois Institute of Technology, Chicago, a Technical Adviser to Northrop Corporation and an Assistant Professor in the Department of Neurosurgery at Rush-Presbyterian-St. Luke's Medical Center, Chicago. His professional interests include the design and packaging of electronic assemblies for implantation in the human body and polymeric protection of thin-film devices.