Pre-pulse Stimulation Capability of a Research Implantable Stimulator System

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Abstract
Theoretical stimulation waveforms were implemented for bench testing on a research implantable pulse generator system for testing of safety and efficacy. The waveforms each consisted of a conditioning “pre-pulse” phase (e.g., a depolarizing pre-pulse) a stimulation phase, and a passive recharge phase. They were bench tested in a completely electronic system and in a saline model. The waveforms were generated by combining multiple timing generators in the research system, each capable of producing a standard clinical stimulation waveform.

1. INTRODUCTION
Electrical stimulation of the nervous system is widely used clinically to treat a host of indications, including pain, movement disorders, deafness, and others. Commercial stimulation devices generate single square pulses (either voltage or current regulated) of short duration (<1000 µs) to excite a target neuron population, followed by a longer duration (ones of ms) phase of opposite polarity to recover charge injected at the electrode. Stimulation with single square pulses is theorized to excite the largest axons closest to the electrode (ROI) first, followed by excitation of fibers successively farther away and/or of smaller diameters as the amplitude is increased. Stimulation protocols that allow populations of neurons within the region of interest (ROI) to be selectively stimulated, e.g., stimulation of fibers of passage without stimulating local cells [1], or stimulation of distal fibers before proximal fibers [2] have been theorized. These pulsing strategies consist of conditioning pre-pulses just prior to delivery of the pulse intended to stimulate target fibers.

While experimental testing has been done in animals, and even humans [3], these stimulation strategies have not been widely implemented clinically, most likely because commercial stimulation systems do not implement them. The present paper illustrates the implementation of two theorized pulsing strategies for selective stimulation on a research implantable pulse generator system (rIPGs) that can be used to test safety and efficacy, developed by Advanced Bionics Corporation.

2. METHODS
Pulsing strategies for selective stimulation may consist of a standard stimulation waveform with one or more additional conditioning pulses. The rIPGs has multiple timing generators, each capable of generating a standard stimulation waveform (stimulation pulse followed by recharge pulse). Programmed correctly, the pulses generated by each timing generator can be combined to generate a conditioning pulse, followed by a stimulation pulse, followed by a recharge pulse.

In the present study, the rIPGs was custom programmed such that one timing generator was used to generate a conditioning pulse, and a second timing generator was used to generate a stimulation pulse that immediately followed the conditioning pulse, and a recharge pulse of long duration.

Two pulsing strategies were implemented: the depolarizing pre-pulse (DPP) waveform that consisted of a 500 µs conditioning pulse and 500 µs stimulation pulse of the same polarity [2], and an asymmetric charge balanced biphasic (ACBB) waveform that consisted of a 900 µs first phase followed by a 90 µs second phase of opposite polarity [1],[3]. In the DPP, the first and second phases had programmed amplitudes of 3.5 and 5.0 mA (arbitrarily chosen), respectively. In the ACBB, the first and second phases had programmed amplitudes of 0.5 and 5 mA, respectively. Both waveforms
had a third passive recharge phase that began 100 µs after the stimulation pulse and that was 6 ms in duration.

A bench test was performed that consisted of an Advanced Bionics 2x8 Artisan™ paddle lead in saline, with source and sink (for the stimulation phase) contacts at opposite ends of the array (~30.8 mm separation) and with the adjacent contacts (on the second column of 8 contacts) used as recording/reference electrodes.

3. RESULTS

The DPP and ACBB waveforms generated by the rIPGs were recorded in a bench test across a resistor, and are illustrated in Fig. 1. The waveforms recorded in the saline experiment are illustrated in Fig. 2. Note that controlled-current sources were used in the rIPGs, manifested by the constant voltage across the resistor (Fig. 1) during active phases, even though coupling capacitors were included at the outputs of the rIPGs. The programmed waveforms were also readily observed in the saline records (Fig. 2). Note that in these experiments the electrode-saline capacitance and properties of the saline resulted in transients observed in the record. A limitation of recording electrodes is that they have an associated electrode-medium capacitance [4]. Also note that the recharge current of the ACBB waveform was not readily observable (at the presented scales) when measured across a resistor, but was observed in the saline model.

![Figure 2: Records of non-standard stimulation waveforms generated by the rIPGs and measured in a saline model. The DPP and ACBB waveforms are in blue and red, respectively. A 16-contact paddle lead was used in the saline model, and 2 contacts not used for stimulation were used for recording.](image)

4. DISCUSSION AND CONCLUSIONS

Theoretically useful waveforms not used in the clinical setting were generated in a research IPG system (rIPGs) used to assess safety and efficacy. The strategy of using multiple timing generators was useful for generating the desired pulses. Measures to ensure absence of charge build up are important, as evidenced by the finite recharge phase observed in the voltage record of the ACBB waveform in the saline model.

References


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