Safety Studies for a Prototype Nucleus 22 Channel Implant at High Stimulation Rates

P.M.Carter[1], R.K.Shepherd[2] and J.F.Patrick[1]
[1]Cochlear Pty. Ltd. P.O.Box 629, Lane Cove 2066
[2]Cooperative Research Centre for Cochlear Implant, Speech and Hearing Research. 384-388 Albert St, East Melbourne 3002
AUSTRALIA

The safe stimulation of neural tissue requires that the stimulation does not produce any toxic electrochemical by-products and that the nerves are not damaged by the very act of responding to the stimulation. The Nucleus stimulator has been proven safe in several chronic animal studies using pulse rates of up to 500 pps and stimulus levels that produced sensations of moderate loudness, and subsequently in clinical use by more that 10,000 patients. Additional safety studies are necessary before considering the use of the Nucleus stimulator at higher rates. This paper describes in vitro investigations using such high rates while animal studies are currently under way to examine the effects of chronic, high rate stimulation.

If the average current into the electrode is not equal to the average current out of it, then the net current must be the result of irreversible electrochemical reactions, some of which may be toxic. The absence of such an average current does not in itself guarantee that there are not equal and opposite irreversible reactions at the electrode, but in the Nucleus system the measurement of average or direct current provides a simple measure of electrochemical performance. This is in contrast to capacitively coupled electrode systems, where the capacitors can provide assurance that there is no long term current flow but may still allow sufficient transient charge to flow to generate toxic by-products [Brummer and Turner, IEEE Trans. BME 24:59-63 (1977)].

In the above animal studies using the Nucleus system, stimulating at rates up to 500 pps at clinically representative stimulus levels, the mean direct current is invariably measured to be less than 100 nA. This study measured the mean direct current, in vitro, at high stimulation rates (>6 kHz), again using a clinically representative range of stimuli. It was found that even for the highest rate and minimum shorting period between stimuli (7 μS), this current was less than 300 nA. These laboratory tests indicate that the Nucleus system of charge recovery is also effective at high stimulus rates. The results are supported by an analysis.

Author/s:
Carter, P. M.; Shepherd, R. K.; Patrick, J. F.

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