AN IMPLANTABLE CUFF ELECTRODE FOR COLLISION BLOCK OF PUDENDAL NERVE MOTOR ACTIVITY

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ABSTRACT

In this paper we present results from acute and chronic animal studies using an implantable cuff electrode system for collision block of motor activity in pudendal nerve. The necessary quasi-trapezoidal stimulus parameters for acute and chronic collision block generation have been characterized and are discussed.

INTRODUCTION

Attempts to restore voiding function in patients with neurogenic bladders through electrical stimulation can potentially use electrodes located on the bladder, within the spinal cord, on the pelvic nerves or at the spinal roots. However, as Schmidt [4] has stated in his review of neurostimulation for bladder control ..."attempts to evacuate the neurogenic bladder have always been frustrated by the simultaneous contraction of the bladder with the urinary sphincter". Such undesirable dyssynergic co-contraction of the sphincter can be greatly reduced through neurotomy of the pudendal nerves. However, neurotomies may render the patient incontinent and can compromise sexual function. We have therefore designed [5], modelled [1] and tested in a dog pudendal nerve / urethral sphincter preparation a prototype nerve cuff technique (so-called Asymmetric Two Electrode Cuffs, i.e. ATECs) for temporarily and reversibly blocking by collision pudendal nerve motor activity. Such a collision block should enable sphincter relaxation during electrostimulation of the bladder; and therefore greatly improve electrically induced voiding efficiency.

Our collision block technique is based on a nerve cuff electrode implant and unique stimulation paradigm designed to produce only antidromic unidirectionally propagating action potentials (AUPAPs) on the myelinated motor efferents of the pudendal nerves. When an AUPAP meets an orthodromic action potential a collision and mutual annihilation occurs [6]. In this way naturally generated or electrically induced orthodromic activity can be prevented from reaching an end organ such as the periurethral sphincter musculature. The ATEC design (Fig. 1) produces AUPAPs by eliciting excitation of the motor axons in a nerve trunk beneath a ring cathode and, simultaneously, abolishing orthodromic conduction at a ring anode of larger diameter. For every quasi-trapezoidal regulated current stimulus injected, a volley of AUPAPs will be produced (stimulus parameters = current amplitude, pulse width, and an exponential 90% to 10% fall-time needed to suppress anode break excitation). A major advantage of this technique is that a synchronous frequency train of stimuli can be used to block by collision asynchronous motor activity [2].

In this paper we present the results of both acute and chronic testing of the ATEC system, implemented in a "spiral" cuff design [3], on dog pudendal nerve. The objectives of the acute experiments were (i) to locate the stimulus parameter "operating point" where a volley of pudendal motor AUPAPs could be most effectively generated while minimizing total charge injection per stimulus, and (ii) to test the effectiveness of AUPAP based collision block as a function of stimulus characteristics (frequency and monophasic or balanced-charge biphasic). The objective of the chronic animal experiments was to study the effectiveness and safety of one month unilateral pudendal nerve ATEC implants.

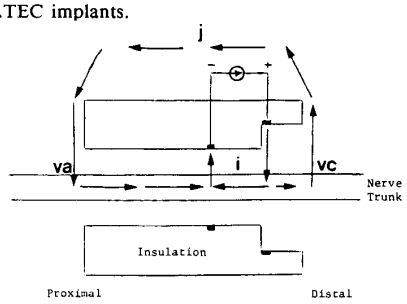

Fig. 1 Cross-sectional view of the ATEC implant. The system "operating point" occurs when current path "i" elicits AUPAPs and path "j" does not produce significant virtual anode (va) or virtual cathode (vc) effects.

ACUTE EXPERIMENTAL METHODS AND RESULTS

In five acute experiments on mongrel male dogs the animals were first tranquilzed with subcutaneous injections of Rompun^R and Promace^R, or Innovar-Vet^R, and then anesthetized using intravenous injections of sodium pentobarbital. One pudendal nerve trunk was surgically isolated within the ischiorectal fossa. An ATEC nerve cuff was placed around the trunk (or branch to the urethra) within a pool of body temperature Ringer's solution. The distal (external periurethral sphincter) and proximal (internal sphincter) intraluminal pressure responses, as well as any intravesical (bladder) response, to testing of the ATEC system were measured by introducing a 7F multiple-channel urethral catheter (Mentor Corp.). The operating point mean current level was determined to be 14.2 mA (s.d. = 2.3 mA), the mean pulse width value was 500 usec (s.d. = 71 usec) and the mean exponential fall-time was 840 usec (s.d. = 147 usec). The per cent reductions in distal intraluminal pressure (from maximal obtainable with a single supermaximal stimulating stimulus to that obtained with the operating point stimulus parameters) ranged from 81% to 94%

(mean = 89%; s.d. = 6%). In two of these acute experiments, trains (to 30 Hz) of monophasic or balanced-charge biphasic stimuli (BCB) were successfully used to collision block most pudendal nerve motor activity (electrically elicited proximal to the implant) (Fig. 2). In general, over the frequencies tested, collision block with monophasic trains was only slightly more effective than block with BCB trains.

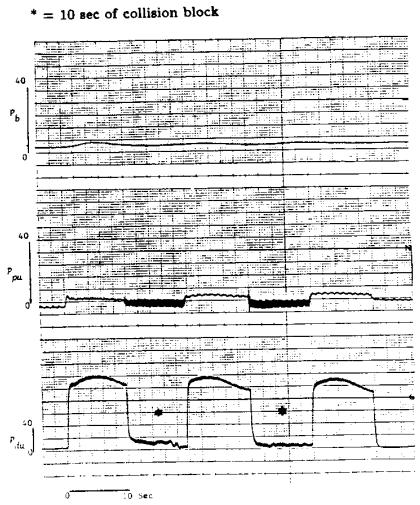

Fig. 2 The distal urethral (P_{du}), proximal urethral (P_{pu}) and bladder (P_b) pressure responses (in cm H_2O) during two ten second periods of 30 Hz BCB collision block of electrically generated pudendal nerve activity.

CHRONIC EXPERIMENTAL METHODS AND RESULTS

In this preliminary study of ATEC long-term effectiveness and safety three mongrel male dogs were implanted with unilateral pudendal nerve cuffs for a period of one month. At the time of implantation each animal was tranquilized (as above), intubated and anesthetized with a gaseous mixture of halothane, nitrous oxide and oxygen. A spiral ATEC implant was placed around one pudendal nerve using aseptic technique. Leads from the implant were tunnelled subcutaneously to a percutaneous exit site between the scapulae. Each animal wore a mesh vest (Alice King Chatham Medical Arts) to protect this site. Animals were maintained on post-op antibiotics as advised by a veterinarian.

At two weeks and four weeks post-implantation each animal was again tranquilized and anesthetized. The same urethral catheter pressure measurement system used in the acute experiments was used to characterize the operating point stimulus parameters and the effectiveness of AUPAP generation. A common finding in these studies was that the maximal obtainable urethral pressure responses were below normal at two weeks, but increased towards the values that would be expected by four weeks post-implantation. We hypothesize that a temporary pressure block at the cuff implant site of some motor axons may have caused this effect.

Over the six testing sessions the mean operating point current level was found to be 8.4 mA (s.d. = 2.7 mA) which represents a significant drop from the value found for the acute experiments (Mann-Whitney U-test P = 0.02). Modelling of the electric field generated by the implant (as in [1]) predicts that encapsulation of the cuff with connective tissue will have such an effect. The mean pulse width value of 500 usec (s.d. = 32 usec) was identical to that obtained in the acute studies. The mean exponential fall-time was 183 usec (s.d. = 160 usec) which is significantly decreased from the acute value (Mann-Whitney U-test P=0.006). This could be possibly due to some fundamental change in the motor axons at the cuff implant (e.g. due to the pressure block) or to an alteration in other intraneural structures (e.g. an increased permeability of the perineurium).

The single stimulus distal intraurethral per cent pressure reduction averaged 83% (s.d. = 9%) and ranged from 73% to 94%. The per cent pressure reduction with 30 Hz AUPAP generation by BCB stimuli (in comparison to 50 Hz supermaximal stimulation) averaged 86% (s.d. = 10%) and ranged from 72% to 95%. It should be noted that these results were very implant dependent. Post-mortem histological analysis of the implanted nerves revealed that (i) some tissue damage to the pudendal nerve in the first implant occurred presumably due to surgical trauma, (ii) temporary formation of a seroma at the implant site of the second animal resulted in significant damage to the nerve, and (iii) virtually no tissue damage was evident in the implanted nerve of the third animal.

CONCLUSION

An implantable cuff electrode technique for collision block of pudendal nerve motor activity has been developed and tested through acute and chronic animal studies. This Asymmetric Two Electrode Cuff design effectively produces the trains of antidromically propagated action potentials needed to implement a collision block of motor signals to the external periurethral sphincter. In future studies we will investigate further the long-term safety of the system and the effectiveness of collision block in combination with sacral root stimulation for producing voiding.

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