ELECTRICAL STIMULATION OF NERVES TO THE LEVATOR AND OCULOROTARY MUSCLES

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ABSTRACT

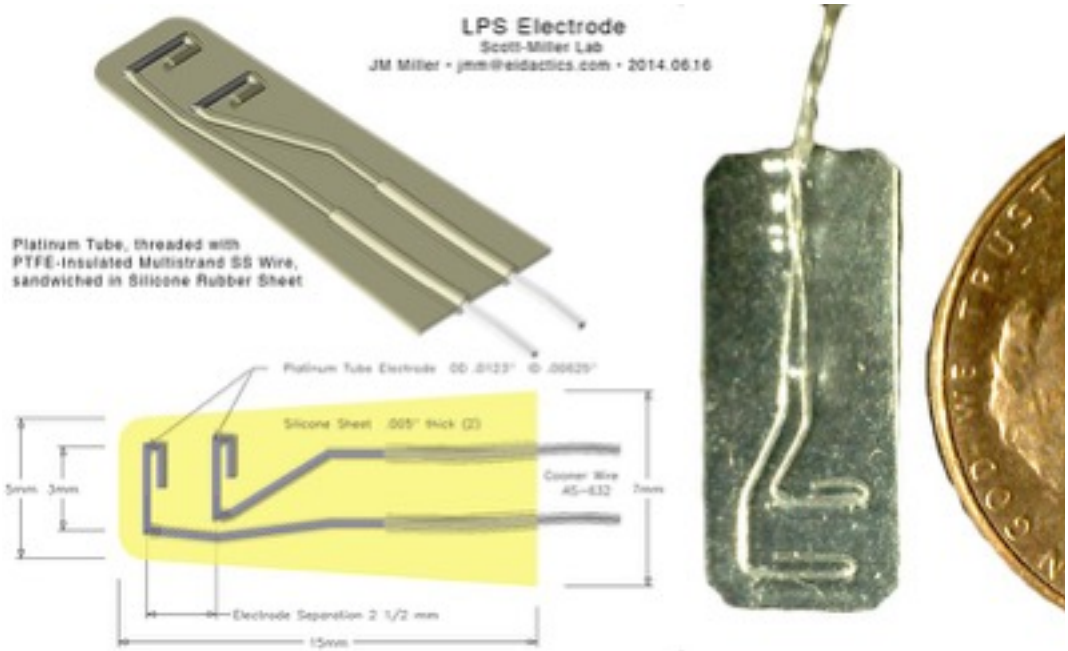
We have developed electrodes and stimulus programs to stimulate the nerves to eye muscles. Effective nerve stimulation can be achieved with less than 1 mA, a small fraction of the current needed for direct muscle stimulation. Initial application will be to the levator palpebrae superioris (LPS) to treat apraxia of lid opening in blepharospasm, probably with clinical trials in about 2 years. Applications to oculorotary muscles will be directed to Duane syndrome, acquired nystagmus, and anomalous innervation syndromes.

INTRODUCTION

Most attempts to influence eye muscle function electrically have used direct electrical stimulation of the muscle itself. Renée Richards implanted such a stimulator in chimpanzee (Personal Communication), David Robins measured electrical parameters and force results in anesthetized cat (Personal Communication), and Federico Velez and his group measured effects of stimulation in the denervated muscles of cats (Velez, et al, 2009). We have found, however, that direct stimulation of eye muscles to functional levels in humans requires currents that are at the limit of pain tolerance.

METHODS

Chronic muscle stimulation electrodes must be effective, robust in a corrosive, dynamic environment, and biocompatible. We've developed a durable, bipolar electrode suitable for stimulating nerves in the posterior orbit supplying the LPS, which minimizes current density at the nerves by encompassing the several nerve branches entering the levator and spanning several nodes of Ranvier. It consists of a 1.0 mm thick silicone envelope carrying fine, cylindrical platinum tubes, bonded to Teflon-covered multi-



strand stainless steel wire leads. Two parallel extents of platinum, each 3 mm long, separated by 2.5 mm, extend outside the envelope to serve as the active electrodes. The envelope is sufficiently stiff to extend posteriorly from stabilizing sutures in the anterior levator to a position determined by delivering test stimuli during surgery. After a few weeks, connective tissue anchors the electrodes firmly in place, and none have migrated or required removal because of tissue reaction. The electrode is shown in the figure.

RESULTS

The levator muscle in rabbit is very similar to that in humans. We implanted the electrode in rabbit LPS and demonstrated effectiveness and durability shortly after implantation, 3 weeks later, and 1 year later. A balanced biphasic current of 0.3-0.9 mA at 250 Hz was found sufficient to lift the lid 2-3 mm, this being roughly 10% of the current required for direct muscle stimulation, greatly reducing power requirements, risk of tissue damage, and apparently eliminating discomfort.

In the linked video, it can be seen that effectiveness is maintained over time, and no discomfort is apparent (see video at: https://drive.google.com/file/d/0B47AcZH5Z0kYWTZrOGNTMkNsNlE/view?usp=sharing).

Histological examination showed no evidence of tissue damage from the implanted electrode.

CONCLUSIONS

An effective and durable electrode was developed, and practical stimulation parameters were found to produce significant lid elevation as long as 1 year after implantation, with no evidence of discomfort or tissue damage. It remains to test effectiveness and safety with a realistic stimulation duty cycle of several hours per day.

In a clinically useful system our electrodes might be driven by an *implantable pulse generator* (IPG) of the type in use for deep brain stimulation. Stimulation would be programmed ON for 6-8 seconds, and OFF for 1 second to allow eyelid closure simulating a blink.

REFERENCES

Velez FG, Isobe J, Zealear D, Judy JW, Edgerton VR, Patnode S, Lee H, Hahn BT (2009). Toward an implantable functional electrical stimulation device to correct strabismus. JAAPOS. vol 13, num 3, pgs 229-235, doi 10.1016/j.jaapos.2008.08.013.