DEVELOPMENT OF A NEW IMPLANTABLE SYSTEM FOR FUNCTIONAL ELECTRICAL STIMULATION IN SENDAI FES PROJECT


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ABSTRACT
We developed a new implantable FES system with 32 output channels. In this system, a RF coil utilizing amorphous magnetic fibers was introduced for increasing transmission efficiency of this telemeter system which transmitted currents for electric power supply to the implanted system and for applying electrical stimulation to the paralyzed muscles. A helically coiled 19 strand rope wound from ultrafine NAS106 stainless steel wires was used as an implantable electrode. The fatigue resistance of this helical NAS106 electrode was much higher than that of the SUS316L electrode which we developed as a percutaneous intra-muscular electrode. We implanted this telemetry system and electrodes to the hindlimbs of three healthy dogs in order to investigate transmission efficiency of the telemeter system and feasibility of this FES system with NAS106 electrodes under the implanted condition.

Keywords: functional electrical stimulation, totally implantable FES system, telemeter, implantable electrode, transmission efficiency

INTRODUCTION
We have used a FES system with percutaneous intramuscular electrodes wound from SUS316L stainless steel wires for restoring motor function of the paralyzed extremities in stroke and spinal cord injury patients1) - 8). Since sterilization of the electrode outlets in the skin surface is always required in this percutaneous system, FES candidates often hesitated to accept this system and showed expectation for the development of a total implant FES system. For this reason, we developed an implantable FES system. In this system, amorphous magnetic fibers was used in the RF coil for increasing transmission efficiency. Implantable electrodes using NAS106 stainless steel wires with high fatigue resistance were also developed. This paper describes evaluation of the system and electrodes through animal experiments.

INSTRUMENTS
System configuration of the totally implantable FES is shown in Fig. 1
1) Stimulus electrodes: The electrode was a helical coil would from a Teflon-coated 19-strand stainless steel rope, which consisted of fine stainless steel NAS106 wires. Each wire diameter was 25 micrometers. According to the rotating-bending fatigue test in air and 0.9%NaCl solution, fatigue properties of newly developed high nitrogen high manganese stainless steel NAS106N were more superior than that of stainless steel SUS316L.
2) Telemeter system: An external processor provided electric power and control signal from outside of body through a transmitting antenna consisting of a 55-millimeter diameter RF coil. A receiving antenna with a diameter of 44-millimeters was set to the surface of the
implantable FES system which faced to the skin side. In either external and internal antennas, the amorphous magnetic fibers was used in order to increase transmission efficiency. This system used 100 kHz carrier waves for power supply and 2 MHz for control signals. This system could supply enough electrical power effectively by means of pulse width modulation using a feedback control signal from the receiving antenna, though a distance between both antennas was changed from 5 to 14 millimeters.

3) Stimulator: The implantable FES system was 60 x 64 x 11 millimeters in size and 68 grams in weight. This system had a stimulation unit with 32 output channels. Pulse width was 0.2 milliseconds, stimulus frequency ranged from 20 to 60 Hz, and pulse amplitude voltage was modulated from 0 to -15 V.

ANIMAL EXPERIMENT

Three adult mongrel dogs were used for testing the efficiency of this implantable system and the quality of the electrode. Their body weights were from 10 to 13 kilogramms.

Under general anesthesia, 16-32 electrodes were implanted to motor points of the bilateral hindlimbs of the dogs. The receiver was fixed to the subcutaneous layer of the back. Distance between receiving antenna and the skin surface of the dog was about 5 millimeter.

Immediately after the operation and one month later, transmission efficiency of the RF coils utilizing amorphous magnetic fibers and the controllability of this totally implanted FES system were examined under general anesthesia.
In order to check the electrode condition, impedance of each electrode implanted was measured 8 months after implantation using a impedance measuring system which was originally developed for impedance measurements of percutaneous intramuscular electrodes.

RESULTS

Until two weeks after implantation, edematous changes and accumulation of the tissue fluid were observed at the implanted site. Thereafter, the FES system implanted was well fixed to the subcutaneous layer.

Acceptable range of side deviation between internal and external RF coils was +/-15mm, while rotation of the coil did not affect the power transmission. In animal experiment, almost the same result was obtained. Therefore, electrical stimulation via this telemetry system caused strong contraction of each muscle and systematic stimulation for realizing locomotive movement provided the dogs with alternating bipedaling movement of the bilateral hindlimbs under general anesthesia.

Even in eight month after electrode implantation, an increase in electrode impedance was not observed in every electrodes (32) in a dog. This may indicate that there was no electrode breakage in this dog.

DISCUSSION

We developed a new implantable FES system with 32 channels and applied to the dogs in order to examine the feasibility of this system. It was found that transmission efficiency of the RF coils using amorphous magnetic fibers was enough to transmit the power and control signals to the implantable FES system. In addition, fatigue resistance of this NAS106 electrode was much higher than a SUS316L electrode which was used for the percutaneous intramuscular electrode. Thus, it was found that the possibility for clinical use of this system seems to be very high.

REFFERNCES
