DEVELOPMENT OF A FINE WIRE ELECTRODE TO STIMULATE PERIPHERAL NERVE BRANCH

— INTRANEURAL ELECTRODE AND HYDROXYAPATITE SKIN BUTTON —

Tamaki,T.*, Akazawa,K.**, Yoshinaga,K.***, and Aoki,H.****

* Orthopaedic Dept., Wakayama Medical College, 9-Bancho, Wakayama, JAPAN
** Dept. of Elect. Eng., Faculty of Eng., Osaka University, Suita, Osaka, JAPAN
*** Orthopaedic Dept , School of Medicine, Chiba University, Chiba, JAPAN
**** Institute for Medical and Dental Engineering, Tokyo Medical and Dental University, Kanda Surugadai, Chiyoda, Tokyo, JAPAN.

Abstract

For the purpose of functional electrical stimulation for patients with spinal cord injury, a fine implantable wire electrode and a new type of percutaneous terminal (hydroxyapatite skin button) were designed, and related basic studies were carried out on rabbits.

The intraneural electrode, an urethane coated platinum-irridium wire of 70 um in diameter, was passed under the epineurium of sciatic nerves of twenty rabbits. Sufficient muscle contraction was obtained, and the possibility of producing selective contraction by stimulating fine nerve branches in a upper extremity of patients with quadriplegia was indicated. Histological examinations over the period of 3 to 10 weeks after the implantation of the intraneural electrode revealed slight reactions, which was regarded to be clinically negligible, surrounding the implanted electrode.

The skin button consisting of the sintered hydroxyapatite and electrical connector was designed and percutaneously fixed through the back skin of rabbits. The hydroxyapatite was closely contacted with the skin tissue and downgrowth of epidermis was not observed.

Key words:
implantable wire electrode, functional electrical stimulation, selective stimulation, hydroxyapatite skin button

INTRODUCTION

The easiest way to stimulate paralyzed muscle cut off from the central nervous system is to apply electrodes to the skin. However, the message sent by surface electrodes can not activate muscles very precisely. To stimulate limbs more accurately, some researchers are implanting tiny electrodes directly into muscle tissue near peripheral nerves or into desired nerve itself (1). Several types of implantable electrodes have been successfully used in recent years. One of the most clinically successful electrode used over extended period has been the nerve cuff electrode which is wrapped loosely around the nerve to be stimulated (2,3). While the cuff electrode has seen much clinical success, the size of the electrode becomes too large to stimulate small nerve branch. The disadvantage becomes much severe when stimulating small nerve fibers innervating hand muscles. Limitation to the cuff electrode prompted a search for an alternative implantable electrode (4,5). The use of small wire electrodes implanted intraneurally was reported by Bowman et al. (5). They reported good success with the electrode. A similar electrode is evaluated as an intraneural electrode in the present study. The electrode used here ,unlike the coiled stainless steel wire used by Bowman, is a flexible fine platinum-irridium wire.

For the purpose of intramuscular stimulation, a stainless steel coiled wire electrode, developed and clinically applied at Case Western Reserve University (6) and Hokkaido University and Shinshu University (7), has been successfuly utilized for many years. The same type of electrodes are also used as the control.

For the totally implanted electrodes, the energy and information parameters needed for stimulation should come through skin. In the last ten years, various materials such as silicon rubber, specially treated carbon and titanium have been used as a percutaneous electrical connector, or "percutaneous button" (1,8). However, these devices have serious problems such as bacterial infection and downgrowth of epidermis, which makes gaps between the device and skin tissue. One of the authors, H.Aoki, has developed a new type of percutaneous device (skin button), made of the sintered hydroxyapatite (HAp), which has superior compatibility with bone tissue and skin tissue (9). It was showed by the long-term implantation ranging from 3 to 17 months that the depth of epidermis downgrowth was limited to only 1 mm (10). The same type of percutaneous button was used in the present study to confirm the possibility of clinical application to FES. Before utilizing the percutaneous button, a skin tunnel transformer which has been originally developed by Andren et al. (11) is employed to examine effects of electrical current on nerve damage.

The purpose of the present study is to assess the feasibility of utilizing the subepineurium wire electrode for chronic stimulation of small peripheral nerves and the percutaneous button made of the sintered hydroxyapatite.

ELECTRODES

The lead to the nerve or muscle consists of a lead wire and a terminal electrode. The lead wire used here is a stainless steel wire (ten stranded wire, 0.15 mm in diameter, 25-30 cm long). The intraneural electrode was made from urethane coated platinum-irridium wire 70 um in diameter (Fig. 1). The final tip of the wire approximately 5 mm was deinsulated and crimped to a 1/3 circle fine surgical needle of 5mm in length , which was used for inserting the fine wire into the epineurium. Fig.2 shows schematically a procedure of implanting the intraneural electrode. Insertion of the needle through the sciatic epineurium is made at a small angle with respect to the nerve. The needle is passed longitudinally just beneath the epineurium for 3 to 5 mm and brought out again through the epineurium. This is repeated twice. The wire is pulled through the nerve until the deinsulated portion of the wire burried in or beneath the epineurium of the nerve. The needle and excess wire are cut off, and a barb is formed at the tip of the left wire

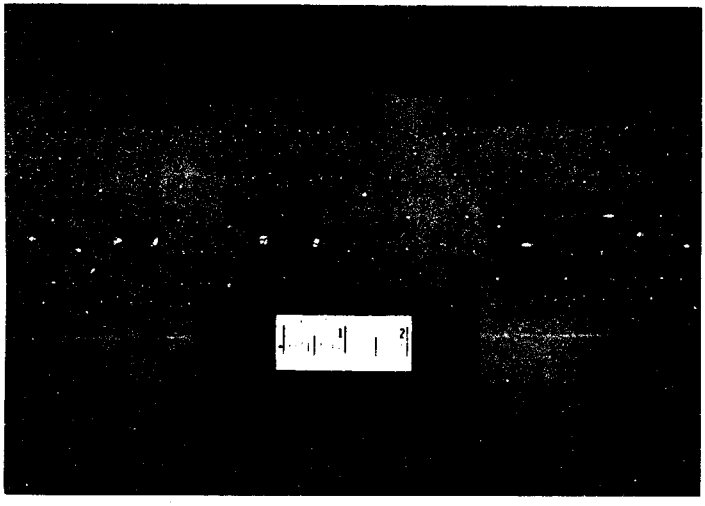

Fig. 1 Urethane insulated platinum-irridium electrode (70 um in diameter) attached to a circle fine surgical needle.

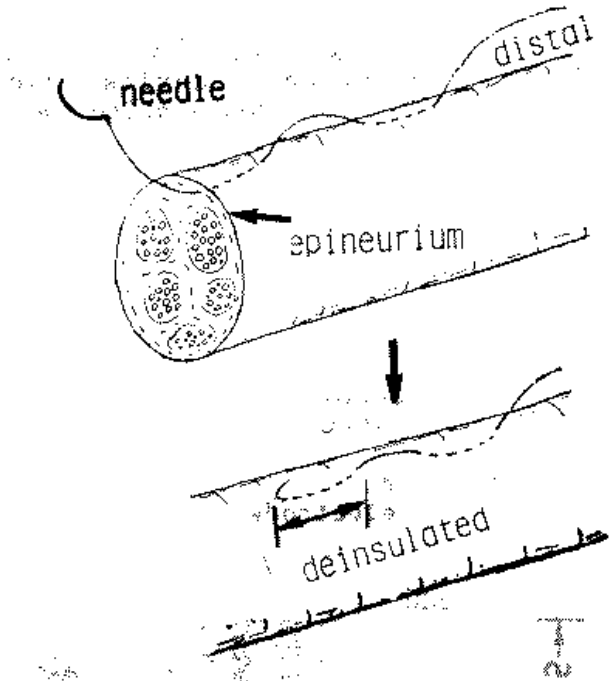

Fig. 2 Pr ire of implanting the intraneural wire electrode into epineurium.

The second electrode is an intramuscular electrode, which is a modified Caldwell electrode described by Peckham et al. (12). This electrode is made from a ten strand teflon-insulated stainless steel wire (type 316; AM Systems; 0.25 mm in diameter) , wound into a helical coil spring. At the tip of the electrode, 10 mm of the insulation is removed and a barb is formed. The electrode is fit into a 23 gauge hyperdermic needle for implantation . The needle containing the wire electrode is inserted into the muscle, and the needle is withdrawn.

SKIN TERMINALS

Two types of skin terminal are used. First one is a new type of percutaneous device, hydroxyapatite skin button made of the Hydroxyapatite, as shown in Fig. 3. The second is a skin tunnel transformer of Fig.4, which was originally designed by Andren et al. (11).

(A) Hydroxyapatite skin button

A button-shaped percutaneous implant made of the sintered hydroxyapatite (HAp skin button) is schematically illustrated in Fig. 3. A four-pin socket is mounted in a straight hole (6 mm in diameter) with resin (STYCAST 1267) and then the epoxy surface is covered with medical grade silicon (Silastic 4210). The lead wires are teflon coated stainless steel wires (0.15 mm in diameter, about 30 cm in length). The first wire is attached to the intraneural electrode, the second and third to the intramuscular electrodes, and the fourth to the indifferent electrode.

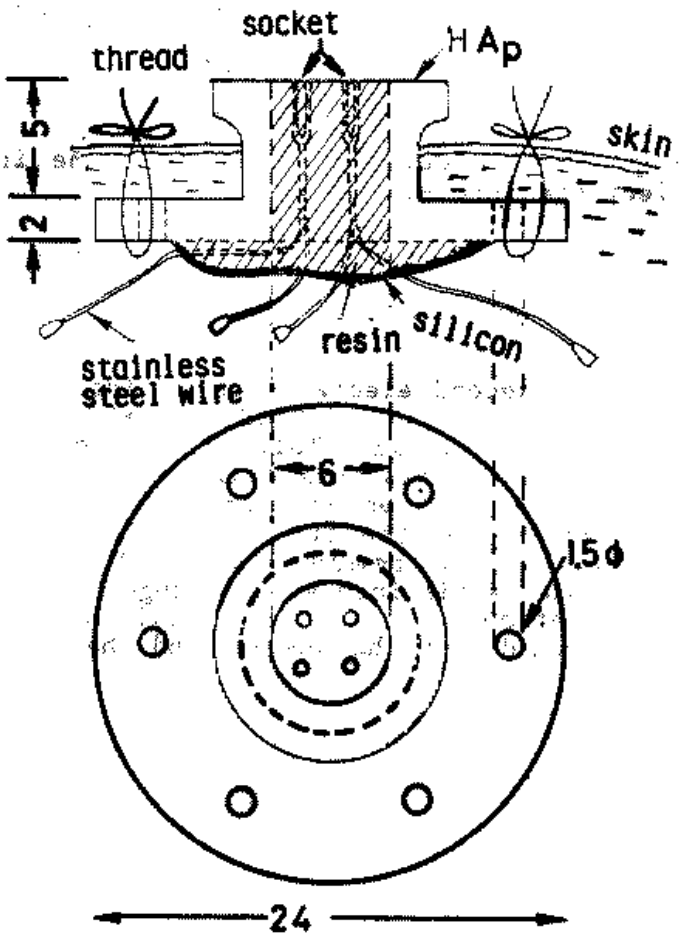

Fig 3 hydroxyapatite skin button through the back of a rabbit.

(B) Skin tunnel transformer

This technique is to transfer electrical energy through the intact skin by means of a skin tunnel transformer, with minimum **risk of infection and** irritation to the skin. **Figure** 4 shows schematically the skin tunnel transformer. The secondary coil **25 mm in** diameter consists of wire which has been buried **in the** skin. Using a surgical technique, skin tube **is created** over the secondary coil, providing a tunnel through **the** center of the burried coil. The primary coil, **the** transformer core (ferrite core, inner diameter **14 mm, outer diameter 22 mm) and the secondary coil construct three adjacent links in a chain. The primary coil is connected to a stimulator. One end of the secondary coil is attached to the intraneural electrode through a connector, and the other to the indifferent electrode.**

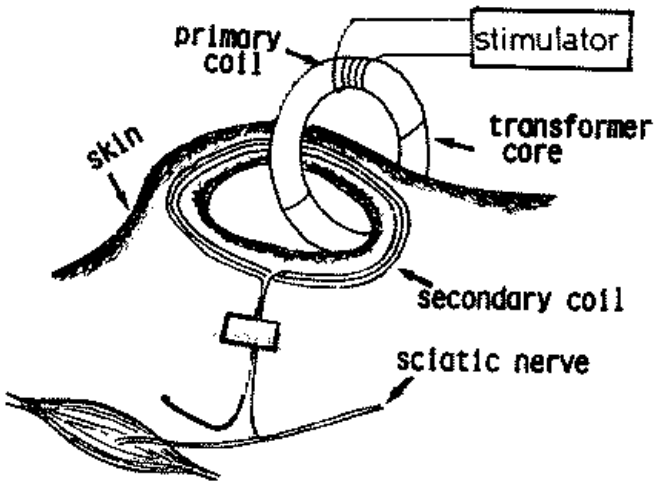

Fig. 4 Skin tunnel transformer

EXPERIMENTAL ARRANGEMENT

Fig. 5 shows an experimental arrangement using the HAp skin button. The stimulator used is of DISA 1500 system. Stimulating currents of both the intraneural electrode and the intramuscular electrode are measured. Neural activities of the sciatic nerve are measured at the point of approximately 1 cm distal from the location of the intraneural electrode, and EMG activities of the gastrocnemius muscle are also monitored. Torque around the ankle joint developed by the contraction of calf muscle is measured with a pair of strain gauges

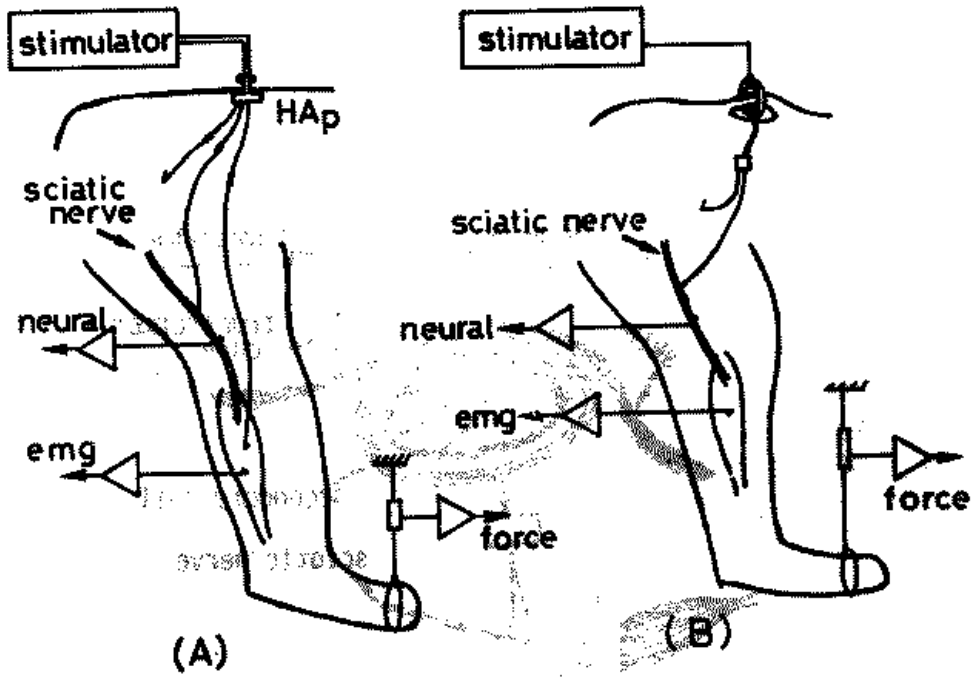

Fig. 5 Experimental set up
(A) Hydroxyapatite skin button system
(B) skin tunnel transformer system.

In the experiment using the skin tunnel transformer, a simple stimulator is designed for stimulating an animal for a long period. Pulse trains (the duration of the pulse is t_1 and the pulse interval is t_1+t_2) are applied for a period T_1, and the rest time (period of no stimulation)is T_1+T_2. Pulses with a carrier frequency of 100 KHz are fed to the primary coil. Output of the secondary coil, rectified and smoothed with diodes and condensors, is fed to the intraneural electrode (Fig. 6). Stimulus condition can be adjusted; the pulse duration t_1 is 0.4-7.5 msec, the pulse interval t_1+t_2 is 15-750 msec, the period of stimulation T_1 is 0.9-4.0 sec and the rest period T_1+T_2 is 1.5-40.0 sec. Voltage between the intraneural and indifferent electrode is measured. Neural activities , EMG activities of the gastrocnemius muscle and torque around the ankle joint are measured.

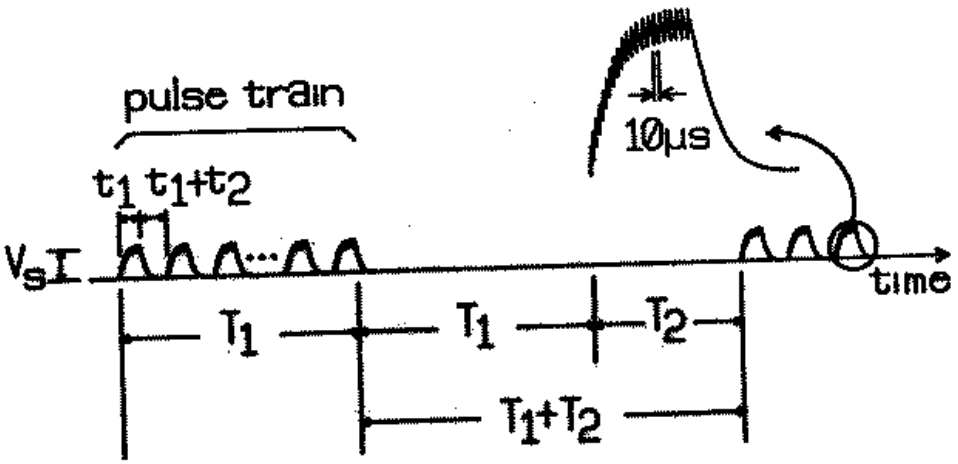

Fig. 6 Waveform of the secondary coil output

PROCEDURE

Twenty Japanese rabbits are used. The animal is anesthetized with Nembutal 25 mg/Kg and N_2O inhalation anesthesia. Firstly, the back skin of the rabbit is opened surgically at the back-waist portion, followed by implantation of either a hydroxyapatite skin button or a skin tunnel transformer. The apatite skin button is fixed with nylon threads by passing through the holes of the lower disk and the skin is then closed with suture (see Fig. 3). The sutures are removed at 10-14 days and then the skin button is allowed to stand free. Antibiotis are injected for three days after the surgery. As for the skin tunnel transformer, both surgical techniques and procedures of the implantation are the same as Andren et al. used. The sciatic nerve is exposed bilaterally at the mid thigh from the proximal thigh to the popliteal fossa. The platinum-irridium fine wire intraneural electrode is implanted in the epineurium of the sciatic nerve by using micro surgical techniques (see Fig. 2). Intramuscular electrodes are implanted in some of the rabbits.

RESULTS

Periodic observation of the rabbits in their cages demonstrated no observable loss of ankle extension function in any of the rabbits implanted both in the case of apatite skin button and skin tunnel transformer. Gross examination of implantation sites of the subepineurium electrodes at sacrifice showed that electrodes had pulled from the nerve and no wire breakages had occurred. After the implantation of HAp skin button, hydroxyapatite was closely contacted with the skin tissue and no observable downgrowth of epidermis was found.

The sciatic nerve was stimulated with the intraneural electrode by means of the HAp skin button. Current threshold of the epineurium ranged approximately 400 uA with the pulse duration of 0.2 msec, and that of the intramuscular electrodes approximately 0.9 mA with the duration of 0.2 msec. When the stimulus current increased above the threshold, intensities of the neural activities of the sciatic nerve, EMG activities of the gastrocnemius muscle and the torque developed were all increased

Similar experiments were carried out by using the skin tunnel transformer. When the stimulus voltage between the intraneural and indifferent electrode increased from 0.5 to 1.3 V, intensities of the neural and EMG activities and developed torque were all increased.

Nerves are examined histologically in some of the animals. At the time of sacrifice the sciatic nerves are excised bilaterally and electrodes removed. Nerve sections are obtained at the levels about 2 cm proximal and through the intraneural electrode site. The sections are stained with Bodian hermis hematoxylin aneosim (H&E). A cross section taken through the electrode site of the nerve implanted for three months without electrical stimulation is shown in Fig. 7. The stain is H&E. The location of the electrode appears as a circular hole. The photomicrograph shows no obvious signs of inflammatory reactions. Fig 8 shows a photomicrograph of the nerve implanted and stimulated for 10 days after the implantation, the stimulation being one hour a day. The stain is Kluger-Barella (K-B). No clear demyelination is found.

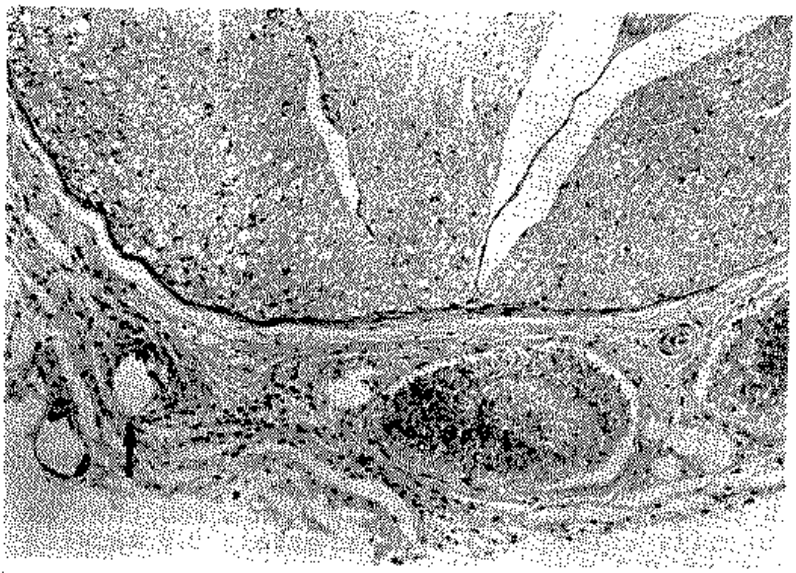

Fig. 7 Photomicrograph of a rabbit nerve implanted for three months and without electrical stimulation. Location of the electrode appears as a circular hole (arrow). H & E stain.

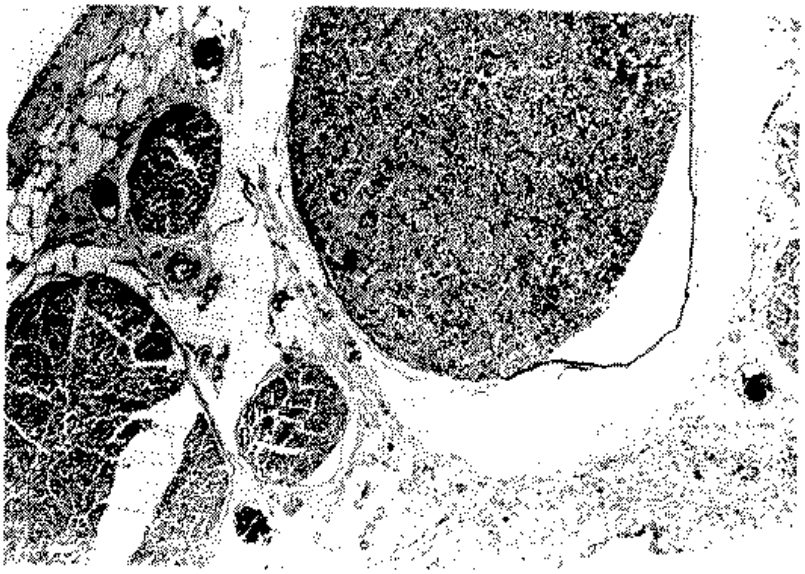

Fig. 8 Rabbit nerve implanted for eight days with stimulation of one hour a day. K-B stain.

DISCUSSION

As a clinically successfuly implant electrode, a wrap around cuff implant electrode has been widely used for stimulating the peroneal nerve of hemiplegic patients or the phrenic nerve of the spinal cord injured patients. To retain more complex functions of the hand or upper arm of the spinal cord injured patients, development of fine electrode capable of stimulating the small nerve has been desired. In this context, the fine wire intraneural electrode inserted into the epineurium of the small peripheral nerves is developed. Results obtained from acute experiments showed high possibility of clinical application; effects of stimulation was sufficient and no significant nerve damage was found. For further confirming the applicability to clinical use, however, it is necessary to implant choronically the fine wire electrodes for a long period and to examine their mechanical strength or to improve their mechanical configuration if the mechanical breakage of the fine wire occured easily.

It is also showed that a percutaneous button made of the sintered hydroxyapatite is clinically applicable, for a long period and without inflammation of infection, to a permanent percutaneous electrical connector system. The period of implant in the present study is not long enough to make definite conclusions for a clinical usage, so that chronic stimulation and longer term implant have to be continued.

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