EPIDURAL CEREBELLAR STIMULATION FOR THE THERAPY OF EPILEPSY IN MAN

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Abstract

The stimulation of cerebellum for the correction of epilepsy seisures has been known since the beginning of the seventies. The results promissing at the beginning became questionable after a larger series of implantations has been carried out. The lack of positive results seems to be hidden in relatively complicated and offensive surgical procedure, unadequate selection of patients and mechanical damage of cerebellar surface due to insertion of electrodes under the dura.

A new technology and a new surgical procedure has been introduced for the epilepsy control. The electrodes are no more placed directly on the cerebellar cortex but epidurally above the cerebellum. The stimulating electrodes are an integral part of the RF powered stimulator and no electrode leads are needed. The surgical technique is a very simple one since the design of the implant enables a "self-locking" of the electrodes to the desired position. The implant is round shaped and has protruding electrodes, which are inserted between the skull and the dura. It is powered from an antenna, connected to the electronic circuitry with settable stimulation parameters according to patient's needs.

Five patients have been treated by means of epidural stimulator in last four years. In all five cases a marked improvement has been observed and no undesirable side effects have been noticed. It seems that the epidural stimulation overcomes the so far used technique and offers some advantages to both surgeon and patient.

Introduction

Epilepsy is a functional disorder which is demonstrated in repetitive states of unconsciousness often accompanied by spasmatic movements. According to the symptoms observed during seisures, epilepsy is divided into a generalised one (grand mal and petit mal) and partial one (psychomotoric and Jackson attacs). Epilepsy is commonly treated by means of chemotherapy or by a surgical intervention when the exact focus is known.

Experiments performed on animals have shown that also electrical stimulation of cerebellar surface can stop an induced epileptic seisure (1,2). Basing on these and other experimental results (3,4,5) Cooper introduced electrical stimulation of cerebellar cortex as an alternative method in cases where the conventional treatment fails (6,7,8). He applied a plate of silicon-coated Dacron mesh with four pairs of platinum-disc electrodes beneath the tentorium cerebelli to the anterior lobe of cerebellum. Using stimulation pulses with 1 ms width and 8-10 pulses per second he succeeded in reducing the number of seisures

in several patients. After the initial results the method gain much attentin and several hundred devices have been implanted not only for the control of epilepsy but also for other deseases such as cerebral palsy.

Though beneficial results were observed, the method became a subject of severe critique. The main arguments against it were the potential damage to the cerebellum, leakage of cerebral spinal fluid (CSF) from the dura and side effects such as ataxia. Also, objections concerning the emotional and financial problems in comparison to the benefit of the device were pointed out (9). Taking into consideration the advantages and the critique of the method, we decided to develop a system which enables the stimulation of the cerebellum with a very simple surgical procedure and a minimal risk for the patient.

Methods and materials

The basic idea was to stimulate the cerebellar cortex epidurally instead of penetrating the dura. Thus the possibility of CSF leakage and mechanical damage of cortex during the electrode insertion was completely eliminated. The electrode leads are very likely to break, so it was decided to eliminate the leads and to keep the electrodes as an integral part of the implantable stimulator. Both epidural placing of electrodes and absence of electrode leads make the surgical procedure simple and short.

The first implantation was performed in 1976. The Ljubljana peroneal implant was used for the purpose. Though it fulfilled the above requirements, the cylindrical shape proved to be unadequate. Therefore a new type of the implant has been designed to meet the specific needs for the implantation in the desired place.

Description of the system

Implant

The implant can be seen in Fig. 1. Basically it is a tuned RF circuit with a rectifying diode. It is disc shaped with dimensions ø 18x7 mm. Electronic components are encapsulated in epoxy resin. The minimal thickness of the protective layer is 2 mm. Care is paid to the position and arranging of circuitry components to minimise the possibility of leakage paths and cristaline growth among them. The electrodes are made from a Pt-Ir 0.6 mm wire and are U-shaped. They are mounted diametrically on the flat surface of the disc and serve also as fixation loops. The implant is powered via an antenna connected to a transmitter.

Controlling external device

Controlling external device consists of a logic programming unit, a pulse generator, and a transmitter with an antenna (Fig. 2). In the programming unit the stimulation sequences are determined by means of binary switches. The signal from the stimulation pulse generator is added to the signal from the programming unit and the sum is fed into the transmitter to power

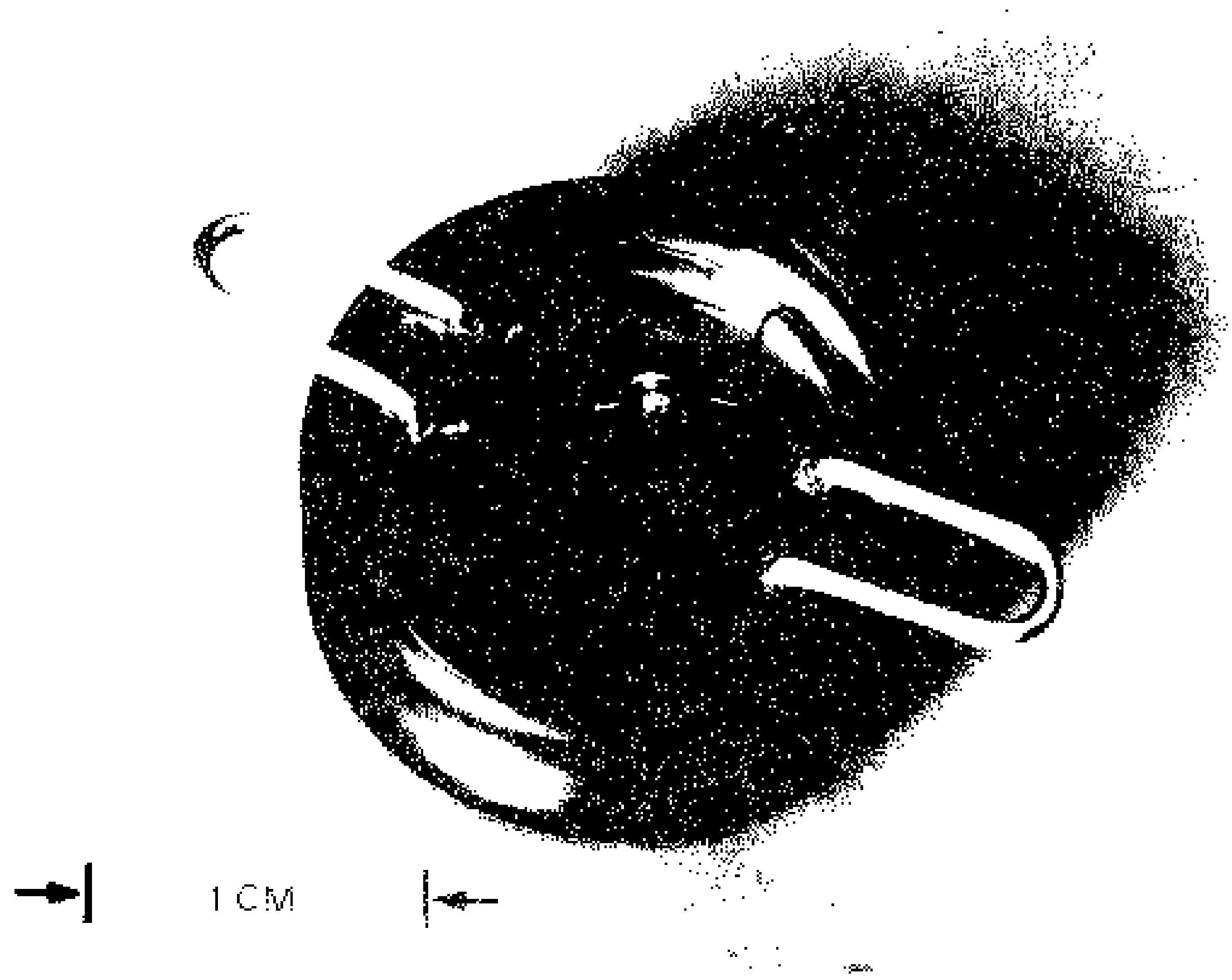

Fig. 1. Implantable cerebellar epidural stimulator

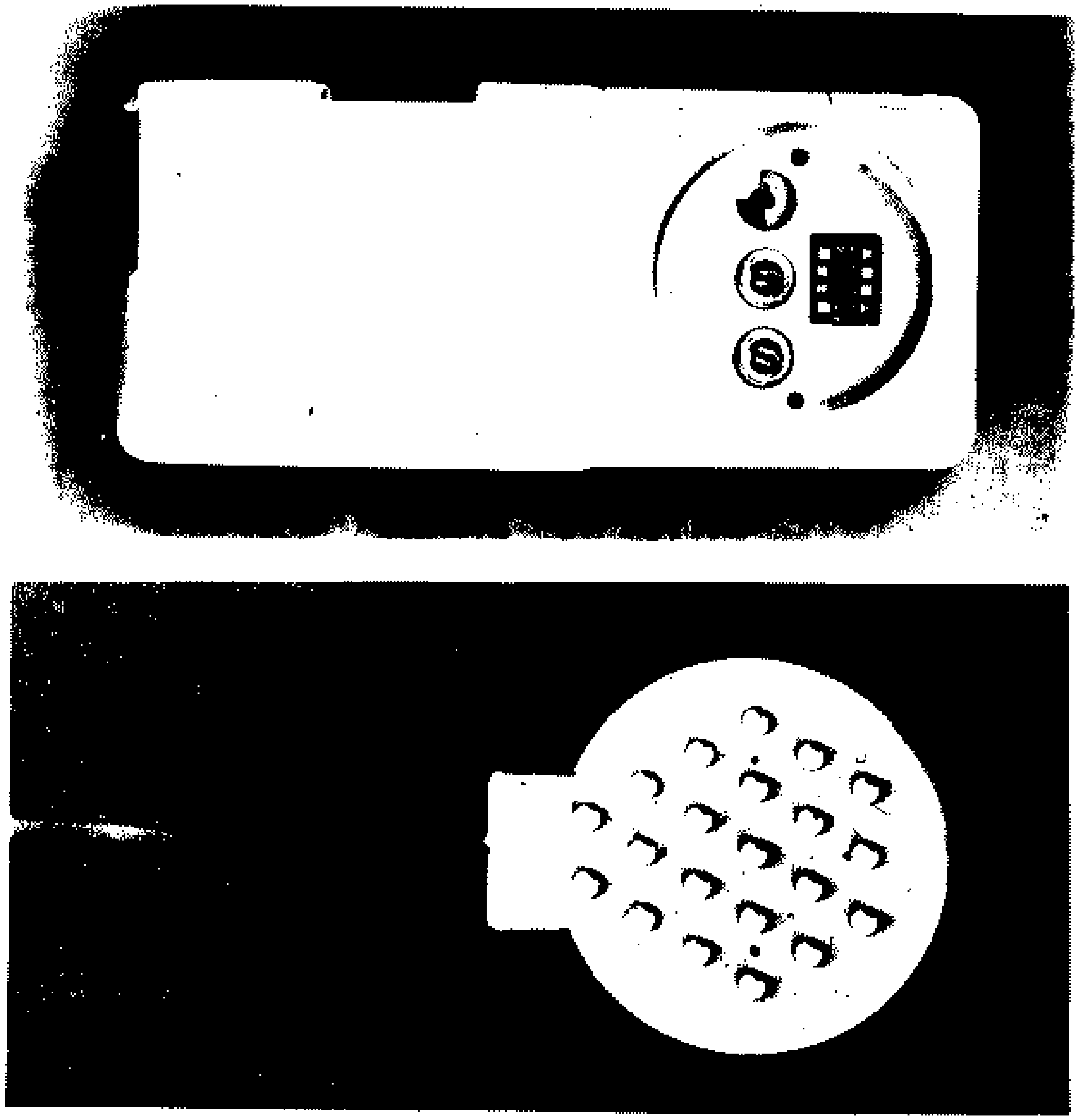

Fig. 2. External controlling unit and the antenna

the implant. The frequency of stimulation pulses can be set between 5 and 50 Hz, its typical value being 12 Hz. The pulse-width is permanently set to 0,6 s. The controlling device has two modes of operation. The first one is continuous operation which is designed for patients with aura, for the control of batteries, and for doctor's convenience. Patients with aura can switch on the continuous stimulation during aura and that way supress the seisure. The second mode of operation is an intermittent one with preset consequent stimulation and no-stimulation periods. The ratio of ON and OFF periods is chosen according to patient's needs. Most commonly, five minutes of stimulation is followed by fifteen minutes without it.

Implantation

The surgical intervention is carried out under general anaesthesia. A oval shaped opening is cut into the right part of the occipital bone (Fig. 3). The implant is pressed against dura so that the protruding electrodes fit into the longer axis of the opening. By turning the implant by 90°, the electrodes lock between the dura and the occipital bone. No further fixation is necessary. The stimulation program begins 14 days after implantation. Fig. 4 shows an X-ray of an implanted stimulator.

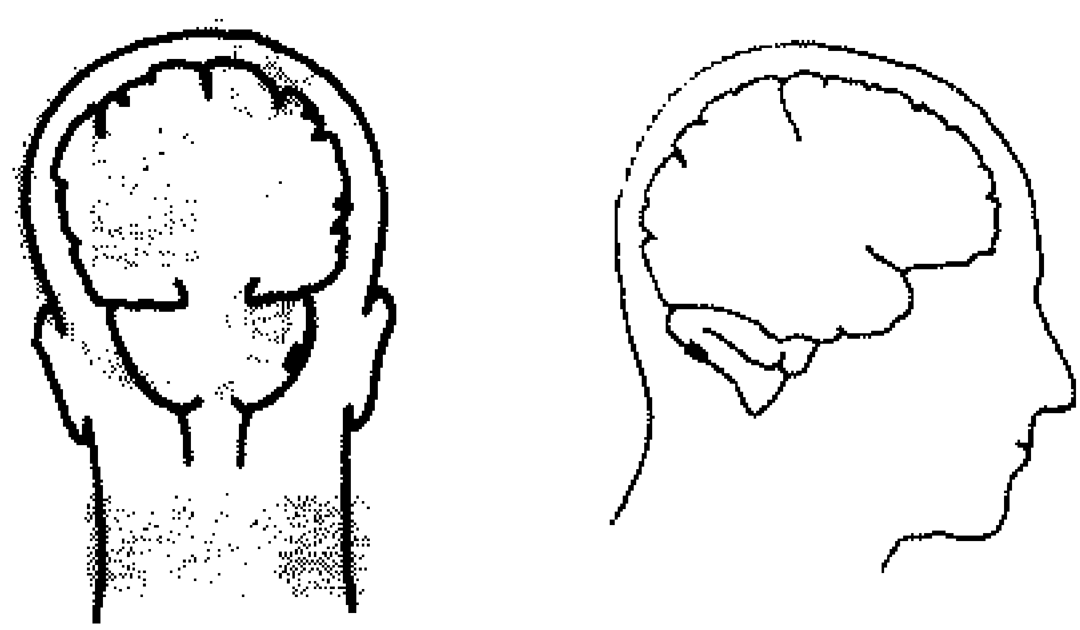

Fig. 3. The site of the implantation

Results

Six patients have been treated by means of epidural cerebellar stimulation since 1976. The last one was operated upon only few weeks ago so that he cannot be taken into the here presented analysis.

In all five patients considerable changes were noticed. Three patients in particular benefited from the device.
- Patient No 1, 26 years, female, had 16 seisures per month prior to implantation. After implantation the seisures appeared only

Fig. 4. X-ray of an implanted stimulator

when the external device failed and when she refused to use it. Patient No 2, 39 years, female had 10 seisures per month prior to implantation. After implantation the seisures appeared only before her period or due to battery exhaustion.
Patient No 3, 26 years, male, had 10 seisures per month prior to operation. After implantation the rate decreased to three seisures in two months. Experimentally the stimulation frequency was changed from 12 Hz to 7 Hz which reduced the rate to 2 seisures in 5 months.
Patient No 4,25 years, male. He was the first patient to use implantable stimulator. According to his own statement, the rate of seisures decreased to 1/3 of that before implantation. This implant was removed 1 year after implantation but the rate of seisures remained low for one more year.
Patient No 5, 42 years, male. This patient had over 40 seisures per month before operation. After implantation the number was reduced to 20 and, what seems to be most important, the severeness of seisures was lessened. Also, prior to operation he had no aura of the forthcomming seisure. Now he feels aura in 2/3 of seisures. In some cases he was able to stop the attack by switching on the continuous stimulation.

In all patients the stimulation was applied two weeks after implantation. The results were not noticed immediately. In few cases it took several months before the patient's condition has been improved. In all patients the chemotherapy remained the same and in same doses as before implantation.

Discussion

According to the results, all the patients have benefited from the described epidural cerebellar stimulation. The surgical procedure appears to be a very simple one and a skillful surgeon can perform it in less than 30 minutes. Hystological analysis was made on the adjacent tissue when the implant was removed from the patient No 4. No significant changes have been noticed, which defines the method as histologically safe. No penetration of dura is necessary and there is no direct contact between the electrodes and the cerebellar cortex. Therefore we believe that the epidural cerebellar stimulation presents a safe and successful tool for the treatment of a certain population of epileptic patients.

Acknowledgement

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