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TREATMENT OF DROP FOOT USING AN IMPLANTABLE PERONEAL UNDERKNEE STIMULATOR

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ABSTRACT. **An implantable peroneal stimulator has been developed to improve the rehabilitation of the drop foot patients who cannot use or refuse the use of conventionally applied peroneal braces. The small size promotes convenient attachment on the stimulation site after a minor surgical intervention. During the past two years twenty implants have been applied. The influence of different stimulation parameters upon the correction of anomalies during walking has been studied using clinical and computer-supported assessment. Possible noxious effects on the peroneal nerve have been studied by measuring nerve conduction velocity. The stimulator is well accepted by patients. Clinical observations show a significant correction of equinovarus and improved gait.**

Key words: **drop foot, functional electrical stimulation, implantable stimulator, gait assessment.**

Electrical stimulation of the peroneal nerve for the correction of a hemiplegic patient's gait has become an established therapeutic and functional method. The stimulation is applied during the swing phase of the affected leg and prevents drop foot, so that the patients walk faster and more securely (8).

To avoid the drawbacks with surface electrode problems we have used implanted electrodes that are permanently positioned on the stimulation site during a surgical procedure. The stimulation pulses are transmitted through the skin by RF radiation. The RF receiver inside the human body transforms bursts of RF energy radiated from the antenna on the skin surface into stimulation pulses and delivers them to the electrodes placed adjacent to the peroneal nerve (Fig. 1).

Several systems of implantable peroneal stimulators have been developed, but their use has been abandoned due to technological, surgical, and commercial problems. Some systems were reliable but the surgery involved was complicated, others required simple surgery but their performances were not satisfactory (1, 3, 7).

Taking advantage of the contemporary advanced technology and using our past experience with implantable stimulators (4) we decided to develop an improved version of the implantable peroneal stimulator and to start a series of implantations to provide patients with a truly functional, reliable, and easily adjustable orthosis.

METHODS AND MATERIALS

Considering the advantages and disadvantages of the known implantable peroneal stimulators the following design requirements were accepted (5, 6):

- the implant should be disc-shaped for better alignment with the antenna,
- no leads are required between the receiver and the electrodes,
- the dimensions must correspond to the implantation site,
- reliable encapsulation must be applied,
- the electrodes must be shaped in such a way that they can also be used as fixation loops in the surgical procedure.

Description of the system

The implant designed and manufactured to meet the above requirements is shown in Fig. 2. Its dimensions are ∅17×8 mm. The electrodes are made of 99.99% pure platinum wire ∅0.7 mm, their surface area being 40 mm^2. The electronic circuit inside implant is protected by medical grade epoxy resin. The transmitting antenna is encapsulated in silicon rubber for flexibility and better hygienic maintenance. The peroneal implant system with the external controlling device is shown in Fig. 3.

Positioning of the antenna on the skin above the implanted stimulator is usually not difficult for the patient. Measurements performed on the implant with the regard to the position of the antenna relatively to the implant show that voltage values remain almost constant within 5 mm of radial displacement, which gives a positioning radius of 1 cm with the same response of the implant and consequently of the nerve. Relative voltage values are plotted against radial displacement in Fig. 4.

The transmitting antenna is energized from a controlling

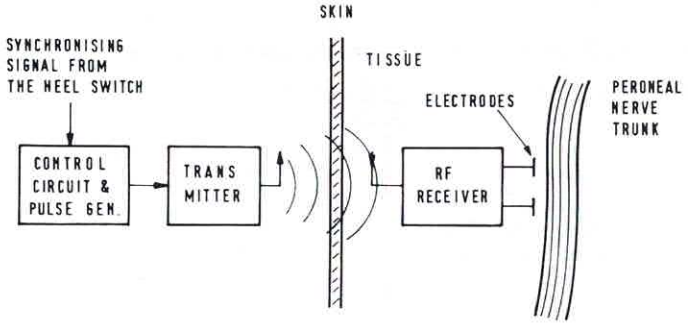

Fig. 1. Block diagram of the implantable peroneal stimulator system.

electronic device which in turn is connected to a sole switch under the patient's affected leg. The stimulation starts after the heel-off phase and stops at the heel-on phase. If the heel-on phase does not occur, the stimulation is turned off automatically after 3 sec.

Stimulation frequency is preset within the controlling circuitry and is typically 33 Hz. The stimulation intensity can be set by changing the pulse width within the range from 0.1 to 0.4 ms using the knob accessible to the patients. (In some cases, as shown later, frequency and pulse-width were slightly changed to obtain functional movement.) The controlling device mounted on the patient on the stimulation site under the knee is shown in Fig. 5.

The frequency used to transmit a signal from the antenna to the implant is 2 MHz, a single AA 1.5 V battery is used as a power source.

Methodology

The patients were selected primarily on the basis of the clinical observations, neurophysiological analysis, and with respect to the results obtained with the surface FES according to the following criteria:

- no further improvement of motor functions can be expected from the patient using conventional methods,
- FES significantly improves patient's gait patern,
- surface FES causes skin irritation or the patient has problems with electrode positioning,
- psychologically, the patient must be communicative and cooperative in the rehabilitation program.

Hemiplegic patients with a fairly long anamnesis were selected who had been using either surface peroneal stimulators FEPA-10, μFES, or a short leg brace. These patients were dissatisfied with their current device and needed a technically better aid.

The methodology of the patient's treatment consisted of:

- kinesiological gait analysis and assessment of anomalies,
- measurement of ground reaction forces,
- FES testing using surface electrodes,
- electrophysiological measurements of muscle EMG in the innervation field of n. peronei, measurements of nerve conduction velocity and M-wave response in order to determine possible mechanical or chemical nox-

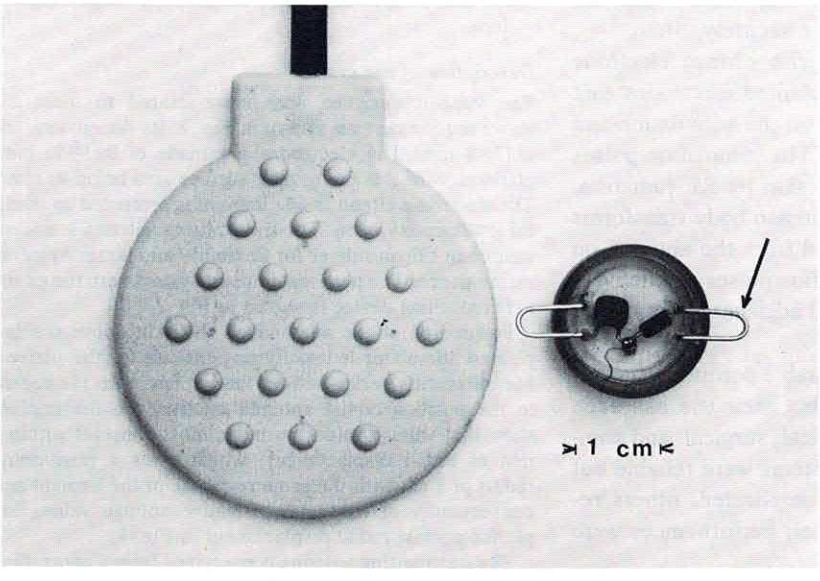

Fig. 2. Implantable peroneal stimulator (on the right) and transmitting antenna (on the left). The arrow shows the electrodes used also as fixation loops.

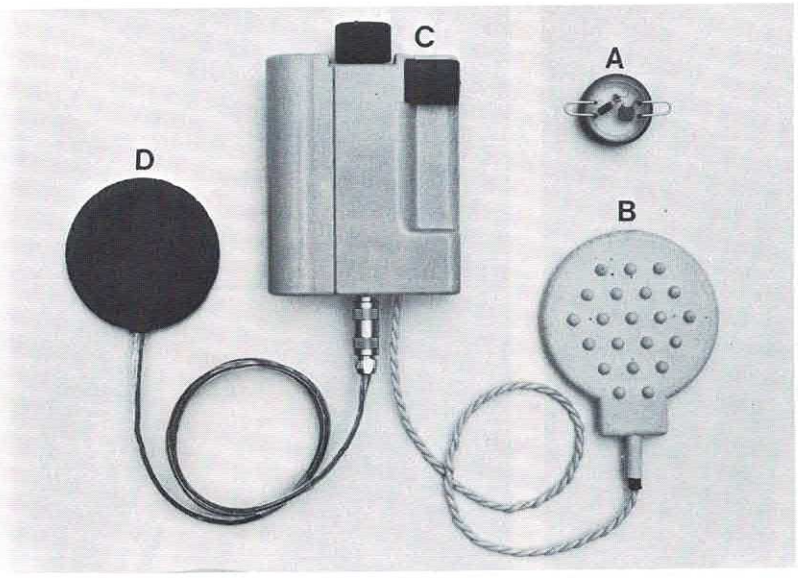

Fig. 3. Implantable peroneal stimulator system: A, implant; B, antenna; C, outer controlling device; D, heel switch.

ious effects of the electrodes being implanted close to the nerve.

In all patients the same measurements were repeated after the onset of stimulation, then after 8 to 12 months and again after 2 years. The functioning of the device was under close observation in order to determine possible defects as well as to register the patients' remarks regarding the application of the device and its use in daily life.

Surgical procedure

The design of the implant with the electrodes being its integral part makes the implantation a minor surgical intervention. The whole procedure takes less than 30 min and is performed under local anaesthesia. An incision is made approximately 2 cm behind the head of the fibula and the peroneal nerve is exposed for a length of 3 cm. The position of the implant is determined using auxiliary electrodes of the same shape as those of the implant. By moving the electrodes along the nerve trunk, and reversing the polarity of the electrodes, the correct functional movement is obtained. The implant is sutured to the determined position using the electrodes as fixation loops.

After the operation, one week's rest is required before the stimulation is applied. The roentgenogram in Fig. 6 shows the position of the implanted stimulator close to the head of the fibula.

RESULTS

In the evaluation of the effects of the new implantable system two assessment methods were applied. Subjective evaluation consisted primarily of visual observations and kinesiological analysis. In all cases it revealed a pronounced correction of equinovarus and improvement in general gait pattern. The results are shown in Table I.

Objective evaluation consisted of measurements of the vertical ground reaction forces produced during walking. Shoes equipped with pressure sensors were used for the purpose. The results so obtained were computer processed and graphically presented (2). The measurements were performed before and after the implantation in order to determine the improvement in the patient's gait.

Fig. 7 shows an example of the measurement of the vertical ground reaction forces. The upper set of curves shows the sum of forces measured by eight pressure sensors mounted on the sole of the shoe. The full lines represent the results before the implantation while the dashed lines show the re-

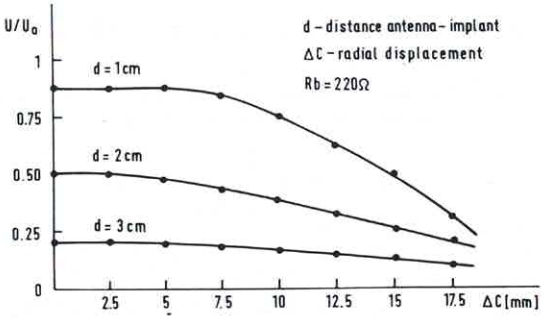

Fig. 4. Dependency of stimulation voltage against radial displacement of the antenna.

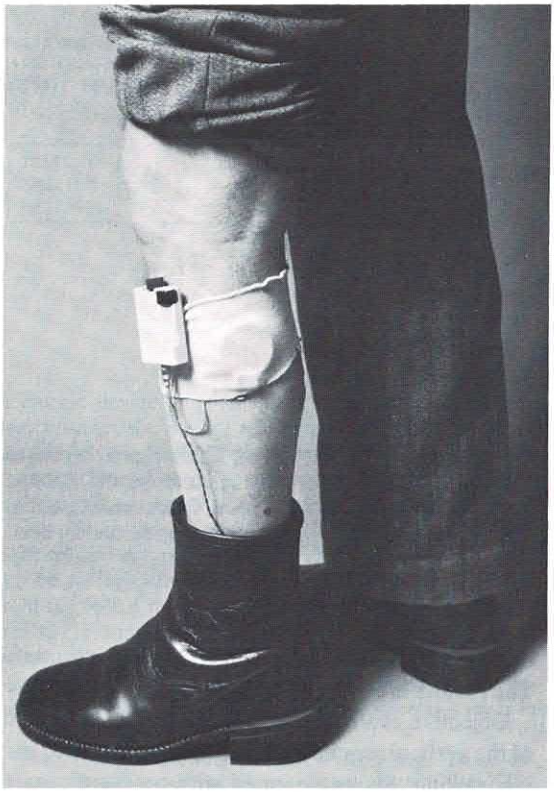

Fig. 5. Position of the stimulation system at the stimulation site.

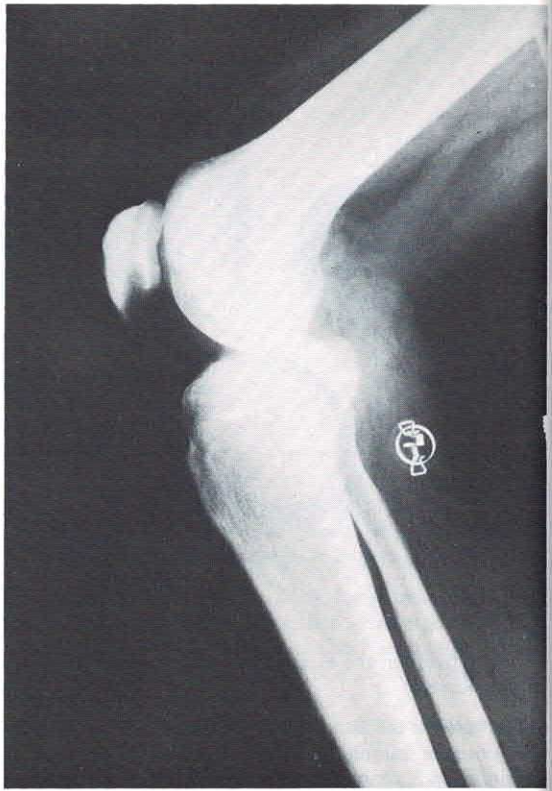

Fig. 6. Roentgenogram of the implanted stimulator behind the head of the fibula.

sults measured after it. The horizontal line marked "bw" denotes the body weight of the patient. It can be seen that during the stance-phase of the affected (right) side the sum of the forces never reaches the body weight. The reason is that the patient was using a crutch. The portion of the support given by this was also measured and is shown as two lower curves under appropriate ground reaction forces. In the abscissa, 100% denotes a normalised full stride time which is 2.23 s for the full line and 1.79 s for the dashed line. Evidently, the patient walked faster using the implant.

Table I. *Correction of anomalies of the impaired gait pattern using the peroneal implantable system (20 patients)*

Level of anomaly: 0= no anomaly, 1= mild, 2= moderate, 3= severe

									After use for 8–12 months							
	Before stim.				With stim.				No stim.				With stim.			
Severity ...	0	1	2	3	0	1	2	3	0	1	2	3	0	1	2	3
Joint																
hip	–	8	7	5	–	14	6	–	–	6	9	5	2	12	6	–
knee	–	6	8	6	–	7	9	4	–	6	9	5	–	8	7	5
ankle	–	–	1	19	19	1	–	–	–	–	1	19	19	1	–	–

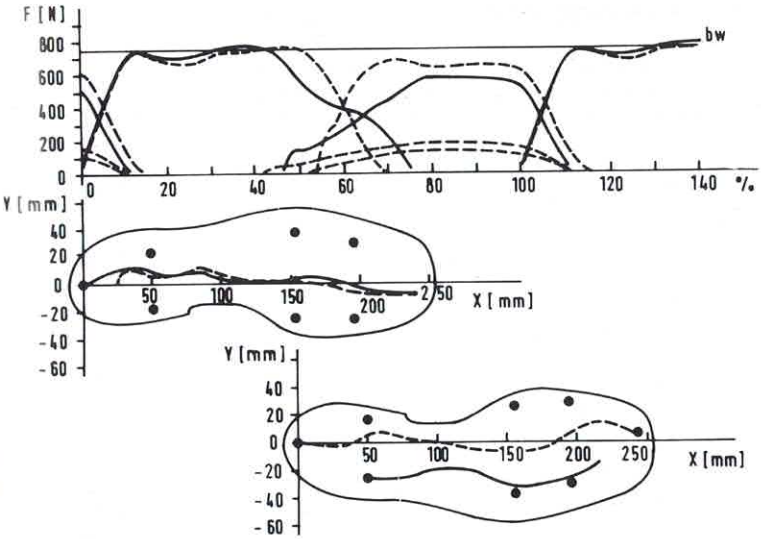

Fig. 7. The typical course of vertical ground reaction forces during walking: —, without stimulation; – – –, with stimulation.

The two foot-prints on the lower part show the location of the 8 pressure sensors (denoted by small circles) and the course of the vertical ground reaction forces. It can be seen that before the implantation the patient was loading his foot too much laterally. After using the implanted stimulator he needed less support by the crutch, the course of the vertical reaction forces moved to the central line of the foot, and more symmetry can be noticed between the left and the right foot.

Electrophysiological measurements confirmed the absence of any noxious effects of stimulation or of the physical presence of the implant close to the peripheral nerve. The functioning of the implantable stimulation system was proved to be reliable and practically without breakdowns. The substitution of deteriorated heel switches was required on several occasions, which is quite normal for this type of orthotic aid.

In one case, after 17 months of continuous use, a stimulator failed to produce the movement. The *x* ray examination revealed displacement of the implant from its original position. As the electrophysiological and histological tests showed no pathological changes either in the nerve or in the surrounding tissue, reimplantation was performed. The extirpated implant showed no change in performance.

The patients' response to the system was closely investigated. All of them were very happy with the new orthosis and most of them had become accustomed to the positioning of the antenna and intensity setting within a few days after the first application. Their walking radius increased after the continuous use of the system, in some patients up to 10 kilometers, even on different ground configurations.

The setting of stimulation parameters to obtain functional movement differed from patient to patient and also in a single patient within a period of time. After some time the muscle response became stable at a certain frequency and pulse-width. Table II reviews the first 20 patients. As seen, in 7 cases the pulse-width had to be reduced below the nominal value of 100 μs.

DISCUSSION

The newly developed implantable peroneal stimulator was evaluated in 20 patients. The results obtained were extremely favourable and point out the advantages of the system as an orthosis. In all cases the surgical procedure was short and was followed by a normal post-operative course. Simple positioning of antenna and effective correction of drop foot also contributed to a longer daily use of the orthosis, an extended walking radius and an increased gait velocity.

As the drop foot condition affects the general gait pattern, the correction of the former also improves the latter, as can be shown from Table I. All patients selected for the implantation had a severe (19

Table II. *Data on patients using implantable peroneal stimulator*

Patient/ sex	Aff. side	Age	Date of impl.	Time after insult	Previous therapy	Stim par.
1 B.J./M	Sin.	50	1.04.81	3.5 y.	Sh. leg Brace	33 Hz 170 μs
2. Z.M./F	Dex.	47	14.05.81	1.5 y.	FEPA-10	35 Hz 150 μs
3. V.J./M	Dex.	50	03.11.81	6 y.	Sh. leg Brace	28 Hz 70 μs
4. Z.D./M	Sin.	32	03.11.81	6.5 y.	FEPA-10	25 Hz 40 μs
5. Z.V./M	Dex.	49	19.12.81	3 y	FEPA-10	33 Hz 40 μs
6. M.F./M	Dex.	38	19.12.81	4.5 y.	FEPA-10	28 Hz 40 μs
7. O.U./F	Dex.	34	14.01.82	3.5 y.	FEPA-10	25 Hz 100 μs
8. H.Z./F	Sin.	34	31.03.82	2.5 y.	FEPA-10	18 Hz 150 μs
9. Z.B./M	Dex	56	31.03.82	6 y.	FEPA-10	19 Hz 300 μs
10. S.B./F	Sin.	67	19.05.82	9 y.	FEPA-10	30 Hz 140 μs
11. M.Z./M	Sin.	25	19.05.82	8 m.	FEPA-10	33 Hz 120 μs
12. C.S./M	Sin.	60	07.07.82	4 y.	Sh. leg Brace	30 Hz 80 μs
13. K.M./F	Sin.	20	15.09.82	7 y.	FEPA-10	33 Hz 270 μs
14. T.M./F	Sin.	58	29.12.82	1 y.	FEPA-10	40 Hz 250 μs
15. P.U./F	Dex.	42	29.12.82	1.5 y.	FEPA-10	40 Hz 140 μs
16. J.R./M	Dex.	46	08.03.83	4 m.	–	25 Hz 20 μs
17. C.A./M	Sin.	39	08.03.83	1 y.	Sh. leg Brace	40 Hz 50 μs
18. P.S./F	Dex.	23	26.04.83	1 y.	–	25 Hz 275 μs
19. P.M./M	Dex.	40	25.10.83	6 y.	μFES	25 Hz 180 μs
20. S.A./M	Dex.	50	17.02.84	4 m.	–	27 Hz 150 μs

cases) or at least moderate level of anomaly in the ankle joint and had a certain level of anomaly in hip and a knee joint. Stimulation of the peroneal nerve improved the level of anomalies in the ankle joint in most patients to a normal condition (19 cases) or to a mild dysfunction (1 case). The same situation was observed after 8–12 months which shows that all patients had been properly selected, i.e. after the restitution had become definite. Similar improvements, though to a lesser extent, can be noted in hip and knee joints. Comparison of their conditions after implantation, and 8–12 months later indicate the extensive use of the device and consequently an improved overall gait pattern.

The study of the stimulation parameters shows that for most patients the correct stimulation frequency was between 25 and 35 Hz. In three cases it had to be increased to 40 Hz and in two cases to be lowered to under 20 Hz to obtain proper functional movement.

The pulse-width was of major interest since it determines the extent of the force exerted by stimulation and also the extent of foot eversion. Therefore the pulse-width needs to be set very precisely to obtain the balanced movement of dorsiflexion and eversion. Originally, the span of pulsewidth settings was between 100 and 400 μs. In clinical application it was established that very few patients

need a pulse-width in exceeding 300 μs while several (7 cases) performed improved walking with a pulse-width setting under 100 μs. This proves that pulse widths in implantable stimulators can be lower than those used in surface stimulators, which normally exceed 150 μs.

The peroneal nerve conduction velocities were measured in all patients. They showed lower figures on the affected side in comparison with the unaffected side, which may be attributed to transsynaptic degeneration, peripheral vasomotor disturbances, decreased temperature of the affected limb and other factors. However, long term application of implanted peroneal stimulators did not show any significant effect on the conduction velocity of the peroneal nerve in this series.

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