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IMPLANTABLE PERONEAL UNDERKNEE STIMULATOR

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Abstract

The electrical stimulation of the peroneal nerve has become an established therapeutic and functional method in the rehabilitation of hemiplegic patients. Besides the surface stimulation, an implantable stimulator can be used for the correction of patients' gait.

In late sixties', peroneal implant was presented by the research group from Ljubljana. Its advatages in comparison to other peroneal implants were small size, simple surgical procedure and absence of electrode leads. In late seveties, an analysis was carried out which showed that almost 40 % of implants had failed due to moisture penetration.

Basing on the results of the analysis, a new peroneal implant was designed with all the advantages of the former implant, and the improvements such as better protective epoxy layer and disc instead of cylindrical shape. Tne changed shape of the implant also required a new transmitting antenna and different shape of stimulation electrodes. Also, new electronic controlling circuitry was developed, small enough to be carried attached to a ribbon under the knee. Dependency of ankle torque on stimulation parameters was carried out for each patient and optimal walking stimulation parameters were determined for 20 patients.

Introduction

Several types of portable peroneal stimulators have come in use after the invention of transistor. In fact they represent the most successful and widely applied use of functional electrical stimulation. This is due to the relatively simple movement required to correct patient's gait and the easily obtained control signal from the heel switch.

Most of the presently used peroneal stimulators use surface electrodes to stimulate the peroneal nerve. The advantage of surface electrodes is that they can be applied to a patient without much effort and preparation. This advantage is so important that it often overweighs the week points. Their poor cosmetic appearance easily revolts patients against FES. Movements of skin against underlying tissue structures may cause low repeatibility of responses on the same stimulation parameters. Drying of electrodes requires their everyday maintenance and repositioning, which often takes patience and

skill since patient's hand is also impaired. Also, uneven drying of water or jelly on the electrode surfaces causes uneven distribution of current density, which in turn may cause skin burns, irritation and pain.

The solution of above problems is the use of totally implanted electrodes, or as often referred to, implantable stimulator. In this case the energy and information concerning stimulation parameters are transmitted through skin as RF radiation. A tuned tank circuit inside the human body receives the energy and the information on stimulation parameters (amplitude, frequency, and pulse width). A rectifying circuit transforms the RF bursts of energy into stimulation pulses which are delivered to excitable tissue via stimulating electrodes.

Several systems of totally implanted electrodes have been developed for stimulating peroneal nerve (1,2) but their production and wide-spread utilisation has been abondoned for several reasons. Inspite of that it was decided to make a new approach to design of an implantable peroneal stimulator with the outer controlling unit small enough to be placed in the vicinity of the implant itself (3).

Requirements and design

Bearing in mind the advantages and disadvantages of so far known implantable stimulators the following requirements were accepted:

- implant has to be disc-shaped,
- electrodes are its integral part,
- dimensions must correspond to the site of implantation,
- the controlling electronic circuity must be small enough to be located close to the stimulation site,
- the performance of the implant must be as little dependent on the displacement of antenna as possible,
- reliable encapsulation must be applied.

The first implantable stimulator manufactured according to the above requirements has been never implanted. During the next developmental stage the shape of the electrodes was changed so that they can be used also as fixation loops during surgical procedure. The implant's dimensions are Ø 17 x 8 mm. The electrodes are made of 99,99 pure Platinum wire Ø 0,7 mm. The electronic circuitry inside implant is encapsulated in Hysol epoxy resin C8-W795/H796. Measurements have shown that this type of epoxy resin absorbs 2,5 % of water in one year and than reaches steady state. Hystological examinations performed in rat proved its biocompatibility which was later on confirmed on man after a case of reimplantation. The new version of the implant with the powering antenna is shown in Fig 1.

Positioning of the antenna on the skin above the implanted stimulator should not require too much skill from the patient and therefore should not be critical. Measurements performed on the implant with the regard to the position of the antenna and the load are shown on Fig 2 and 3. It can be seen that voltage values remain almost constant within 5 mm of displacement. That actually represent a circle with the diameter of 1 cm, where amplitude remains the same.
The antenna is energised from a controlling electronic circuit, which is in turn connected to a sole switch under the patient's affected leg. The stimulation sequence starts immediately after the

heel-on phase. In case that on-phase does not occur, stimulation automatically stops after 3 seconds.

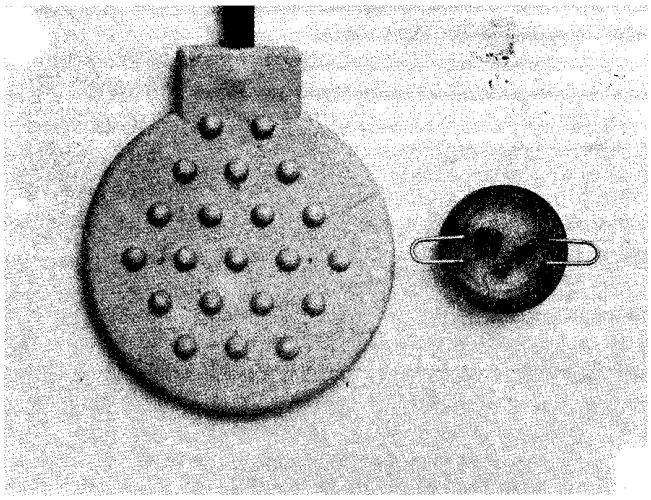

Fig 1 Antenna and implantable stimulator

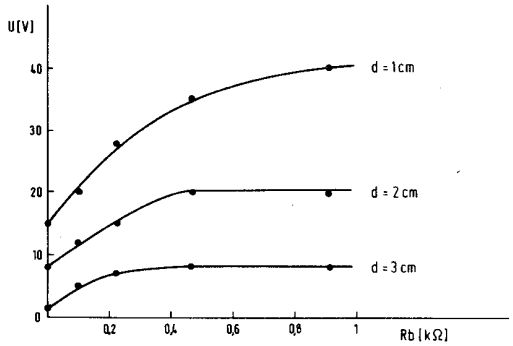

Fig 2 Dependency of voltage on distance and load

Stimulation frequency is internally set within the electronic circuitry and is tipically 33 Hz. The stimulation intensity can be set by changing pulse width in the range from 0,1 to 0,5 ms (in some cases, as shown later, the range had to be broadened).

The transmitting frequency is 2 MHz, a single 1,5 V battery is used as a power source. The electronic controlling system with the antenna attached under the knee is seen in Fig 4.

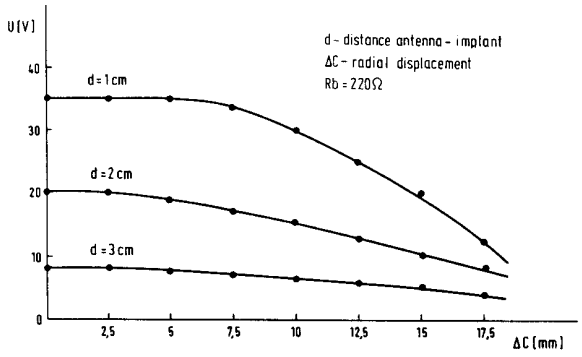

Fig 3 Dependency of voltage on axial and radial displacement

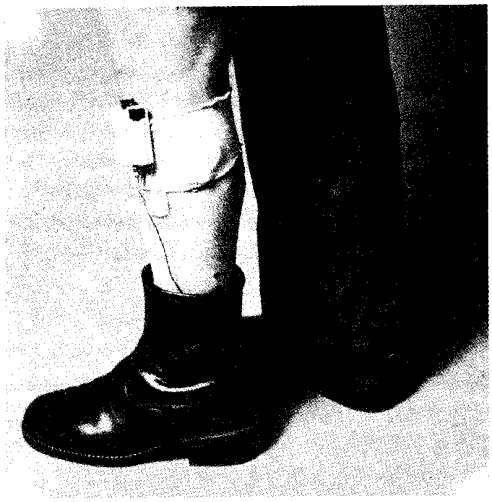

Fig 4 Peroneal stimulation brace placed on its site

Implantation

When applying implantable peroneal stimulator for the correction of foot-drop, the advantage is taken of the nerve anatomic characteristic called funicular plexus. Practically every nerve serves for several purposes and comprises nerve fibres with different destinations. With man, the nerve trunk is composed of funicle-bundles of nerve fibers. Those bundles interweave among themselves so that nerve fibers of one bundle in some distance may enter other bundels. Though the funicular structure of the peroneal nerve is theoretically known, the exact bundles that innervate particular muscles are not known and must by found, during the surgical procedure, by trial. When the nerve is exposed in satisfactory length, the correct movement can be achieved by moving stimulating electrodes along it, and finding the optimal configuration of nerve bundles.
The whole surgical procedure from the first cut to the last stitch lasts less than 30 minutes with the local anaesthesia applied. The length of the cut is approximately 30 mm. During the operation the patient lies on his unaffected side and supports the affected leg with the calf of the healthy leg.

When the nerve is exposed the position of the implant is determined by means of auxiliary electrodes with the same shape as that of the implant's. After the correct movement has been obtained, the implant is sutured to the determined place using electrodes as fixation loops. The correct movement is reconfirmed again with the implant and a sterilised antenna. After operation, a week's rest is required. Fig 5 shows an typical X ray of the implant after implantation.

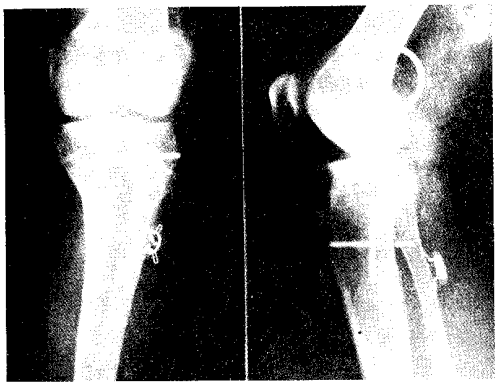

Fig 5 X ray of the implanted stimulator

Patients and stimulation parameters

The original setting of parameters was 33 Hz and 100 to 500 μs where the pulse-width was responsable for the strength of the movement. In most cases, this span was sufficient to cover individual settings for every patient, yet in some patients the parameters had to be changed beyond the standard span as to obtain good functional movements. Table 1 gives exact values that patients use in their daily application of peroneal implantable stimulator. It can be noticed that in 7 cases the pulse width had to be reduced to values under 100μs.

Table 1

patient/ sex	affected side	age	date of implantation	time after insult	previous therapy	stimulat. paramet.
1. B.J./m	sin	50	1.4.1981	3,5 years	sh.leg brace	33 Hz 170 μs
2. Ž.M./f	dex	47	14.5.1981	1,5 years	FEPA-10	35 Hz 150 μs
3. V.J./m	dex	50	3.11.1981	6 years	sh.leg brace	28 Hz 70 μs
4. Z.D./m	sin	32	3.11.1981	6,5 years	FEPA-10	25 Hz 40 μs
5. Z.V./m	dex	49	19.12.1981	3 years	FEPA-10	33 Hz 40 μs
6. M.F./m	dex	38	19.12.1981	4,5 years	FEPA-10	28 Hz 40 μs
7. O.U./f	dex	34	14.1.1982	3,5 years	FEPA-10	25 Hz 100 μs
8. H.Z./f	sin	34	31.3.1982	2,5 years	FEPA-10	18 Hz 150 μs
9. Ž.B./m	dex	56	31.3.1982	6 years	FEPA-10	19 Hz 300 μs
10. Š.B./f	sin	67	19.5.1982	9 years	FEPA-10	30 Hz 140 μs
11. M.Ž./m	sin	25	19.5.1982	8 months	FEPA-10	33 Hz 120 μs
12. Č.Š./m	sin	60	7.7.1982	4 years	sh.leg brace	30 Hz 80 μs
13. K.M./f	sin	20	15.9.1982	7 years	FEPA-10	33 Hz 270 μs
14. T.M./f	sin	58	29.12.1982	1 year	FEPA-10	40 Hz 250 μs
15. P.U./f	dex	42	29.12.1982	1,5 years	FEPA-10	40 Hz 140 μs
16. J.R./m	dex	46	8.3.1983	4 months	-	25 Hz 20 μs
17. C.A./m	sin	39	8.3.1983	1 year	sh.leg brace	40 Hz 50 μs
18. P.Š./f	dex	23	28.4.1983	1 year	-	25 Hz 275 μs
19. P.M./m	dex	40	25.10.1983	6 years	μFES	25 Hz 180 μs
20. Š.A./m	dex	50	17.2.1984	4 months	-	27 Hz 150 μs

Discussion

According to the results all 20 patients have benefited from the described implantable underknee stimulator. They use it daily and all of them claim that they have been become dependent on it and refuse any other orthopaedic aid. The positioning of the powering antenna has proved to be very simple and the only problem that appeares is malfunctioning of the heel switch or breakage of the antenna cable. Hystological analysis of the materials used for the implant has shown no significant changes in tissue, also, no other side effects have appeared.

Acknowledgement:

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