ADVANCED CUTANEOUS ELECTRICAL STIMULATORS FOR PARETIC PATIENTS' PERSONAL USE

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Abstract

Three new functional and/or therapeutic cutaneous electrical stimulators which can be used by paretic patients themselves in non-clinical environment are presented in the paper together with preliminary results of their clinical evaluation. For more successfull application, devices are designed to be simple to operate, more effective taking in account recent discoveries, smaller, and cosmetically more acceptable. Underknee peroneal stimulator FESE–L2 is the smallest and is designed to be placed in the stimulated area itself. With fixed pulse width (0,15 ms) and frequency of stimulating pulses (25 Hz), it has an adjustable stimulation sequence and adapts itself automatically to the walking rate of the patient. It is powered by a single 1,5 V penlight cell and acts without on-off switch. Stimulation is triggered by heel switch, patient controls only stimulation voltage (10 to 130 V). Hand prehension stimulator FESE–H3 proportionally controlled by lifting of a shoulder, has an adjustable pulse width (0,05 to 0,7 ms), frequency of stimulating pulses (20 to 50 Hz), and stimulation threshold voltage (20 to 50 V). These adjustements are not accessible for the patient who controls only stimulation voltage (from threshold to 120 V) and chooses proportional or therapeutic mode where on–off stimulation is triggered by built-in cycler. The device is powered by a single 9 V transistor battery. Therapeutic stimulator PLS–4 designed for treatment of peripheral and central lesions, has two control panels: patient turns the device on and off and chooses stimulation current (0 to 30 mA) only, while on the covered rear panel, eight stimulation modes (hand or automatically triggered rectangular or exponentially shaped thetanical current pulse trains or long peripheral current pulses) can be chosen. Besides, there are hand triggering push-button and adjustments for stimulation frequency (thetanic: 8 to 80 Hz, peripheral: 0,1 to 1 Hz) and pulse width (thetanic: 0,15 to 1,5 ms, peripheral: 15 to 150 ms). With the stimulator, acoustic conditioning stimulus is included. Powering is achieved by four 1,5 V "D" cells or by a dryfit lead accumulator.

Introduction

Since the invention of functional electrical stimulation as a rehabilitation method, its application in non-clinical environment has been one of its aims as well as the problems. For better results, stimulators should be used intensively with conscious collaboration of patients in their normal environments. Stimulators should be used until with the advanced rehabilitation they are no longer neccessary or where it is not possible, even permanently.

After the first peroneal stimulator was described (1), several such patient oriented electronic devices have been developed and applied (2 – 7). From their application and

evaluation and from the research work which has been going on, some general requirements have emerged. Devices for patients should be simple and versatile together with high efficiency and reliability. They should be small and unobtrusive without long control and stimulating cables while powering should be independent and totaly safe. Patients should not be able to change possible individual presetting of stimulation parameters. The same as research and clinically oriented stimulators, devices for personal use should include in spite of their low cost all recent discoveries. Orthotic devices could also be used therapeutically. And last but not least, devices should be accepted by patients.

In this paper, three new functional and/or therapeutic cutaneous electrical stimulators designed for personal use outside clinical environment are presented. The first two underknee peroneal stimulator FESE–L2 and hand prehension stimulator FESE–H3 – have been designed primarily as orthotic devices while the third – therapeutic stimulator PLS–4 has been designed for treatment of both central and peripheral lesions.

In their design, rather new approach was followed. Besides miniaturisation and simplification of electronic circuitries without restricting efficiency, a lot of attention has been paid to acceptability and functionality of the devices. Orthotic stimulators carried by patients, however small they are, cannot be hidden. Usually, imitations of shape, skin colour etc. lead to even worse results. For successfull application, all prejudices of patients and persons around them should be excluded. Stimulators should become another electronic devices for everyday's use for them and should not be hidden. So, aesthetical outlook of the devices has also been one of the aims during their development. Acception from patients and awards from different exhibitions (Stuttgart, Hannover, Ljubljana) have shown, that this part of work was accomplished successfully.

All three devices are powered by easy available low cost regular batteries. Representing another occupation for patients, accumulators were abandoned. However, therapeutic stimulator is provided with accumulator charger plug. Besides stimulation intensity control, number of connectors and controls for patients are reduced to minimum. Underknee peroneal stimulator operates without on–off switch and has only a control switch connector, hand prehension stimulator has only operating mode switch with proportional control included in stimulator housing itself, while therapeutic stimulator has on–off switch and electrode connector.

Together with the stimulators, new electrodes have been developed starting from already described ones (8). Their flexibility provides better contact with skin. They are molded of silicone rubber and have round shape. Rubber enclosure is filled with sponge while aluminium foil with gold plated snap connector provides electrical contact. Different kinds of sponges or nonwoven tissue can be inserted or replaced without special aids. From reasons of potential skin irritations, nonsynthetic materials have been preferred. Two sizes of electrodes – one with 25 mm (Fig. 1) and another with 50 mm in diameter (Fig. 5 and 6) – have been developed and clinically tested. Both have proved well, specially the smaller one used for stimulation of n. peroneus communis where rigid electrodes placed at the head of the fibula had been rather problematic.

For all three stimulators, clinical evaluation is going on (underknee peroneal stimulator seven months, hand prehension stimulator two (five) years, therapeutic stimulator five years).

Underknee peroneal stimulator FESE–L2

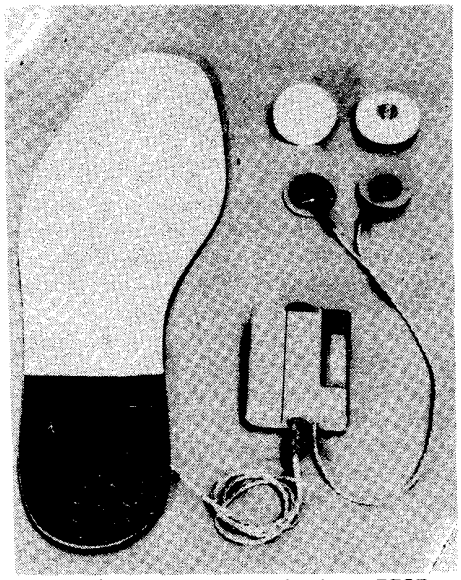

Fig. 1 Underknee peroneal stimulator FESE–L2 with control switch in shoe insole and electrodes. Stimulation sequence adjustment is under the black cover in the upper right edge of the box

Underknee peroneal stimulator FESE–L2 (Fig. 1) is an orthotic and therapeutic electronic aid for patients with upper motor neurone lesions due to injuries of central nervous system and consequential hemiparesis. Originally, it has been designed for electrical stimulation of the peroneal nerve providing so externally controlled synchronized dorsiflexion and eversion of the foot during the swing phase of the gait. The control between predominantly eversion to pure dorsiflexion can be chosen by positioning the electrodes.

With almost matchbox size and 65 grams, underknee peroneal stimulator is the smallest of the three described stimulators. Although it has been designed for functional stimulation of peroneal nerve, it can be applied on other nerves or muscles where on–off stimulation pulse trains with constant amplitude are required. Its small size and simple operation allow its application in stimulated area itself together with electrodes minimizing so wiring problems. When not used as a peroneal stimulator, a convenient control switch is to be connected instead of heel switch. With hand switch, it can be used as therapeutic stimulator.

For the stimulation of n. peroneus communis, the stimulator is attached immediately under the knee (e.g. on the flat part of the tibia) with surface electrodes placed laterally of the knee and at the head of the fibula, all being held in place by an elastic knee support. The control switch in the shoe insole under the heel of the impaired leg is connected with the stimulator by a cable (Fig. 2).

With voltage output between 10 and 130 volts, frequency of stimulating pulses and their pulse width are preset to optimal values of 25 Hz and 0.15 ms according to fatiguing of the muscles, sensations of patients and power consumption of the device (9,10). Requiring practically no energy, CMOS control circuitry and pulse generator are permanently connected to the battery. Energy consuming part of the whole circuitry is turned on and off by the input control signal only when neccessary, which extends the battery life significantly. On–off switch is thus no more neccessary, patients choose stimulation intensity only.

The stimulating electrical pulse train is triggered by lifting the heel of the impaired leg during the push–off phase and is turned off by the landing of the heel in the initial stance phase of the gait providing so optimal fully walking rate dependent stimulation (11).

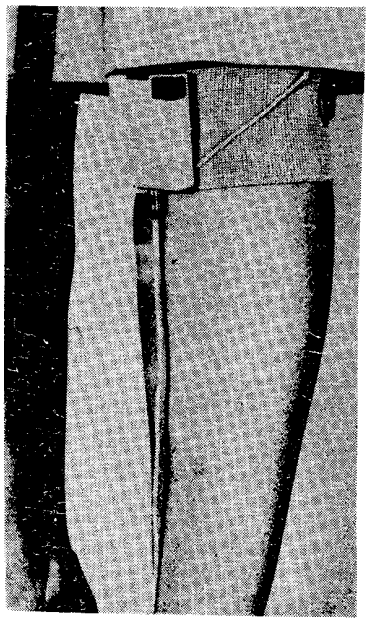

Fig. 2 Underknee peroneal stimulator FESE–L2 applied for stimulation of n.peroneus communis

The stimulator turns–off by itself after 3 seconds in the absence of heel contact preventing continuous stimulation when the impaired leg is lifted for a long time or when the stimulator is detached from the leg.

Following the research, when the stimulation of individual muscles should occur during the gait cycle (12,13) and the timing of EMG activity of normal persons (14), the stimulator provides an adjustable stimulation sequence which should be set by the therapist for each patient individually. This adjustment is protected with the cover and is not accessible to patients (Fig. 1). An adjustable initial delay of stimulation up to 350ms after lifting of heel allows at least passive push–off movement at the beginning of the swing phase of gait. It also ensures that short liftings of the heel that do not imply the beginning of the swing phase (e.g. turning around or shifting the weight) do not produce stimulation. The delay can be omitted with patients who used to obtain eversion only and with those where stimulation in the terminal stance phase helps inhibiting spasms of antagonistic muscles. It can be omitted also when the device is not used as a peroneal stimulator. The other delay after landing of the heel (100ms) allows stimulation in the initial stance phase to reduce the impact of the leg with the ground and to prevent foot slap.

The underknee peroneal stimulator FESE–L2 is powered by a single regular 1.5 volt penlight cell. Battery instalation can be performed by patients themselves with no possibility of setting wrong polarity. With one hour average daily activity, low cost zinc carbon cell should last 20 days approximately and an alkaline cell considerably longer.

Preliminary version prototype of underknee peroneal stimulator has been clinically tested on fifteen patients for seven months. Sessions with patients lasted for 20 to 90 minutes every second to fourth day. Each patient had his own elastic knee support with his electrode position on it. Patients were able to position the electrodes and the heel switch, to attach the stimulator and set proper stimulation intensity by themselves. The preliminary version prototype performed well.

Hand prehension stimulator FESE–H3

Hand prehension stimulator FESE–H3 (Fig. 3) is also indicated for patients who have last volitional control of movements due to a central neurone lesion and for those with muscle atrophy, partially denervated muscles and psychogenic paresis. The stimulator has been designed primarilly to open the hand by electrical stimulation. By positioning the electrodes, control among dorsiflexion of wrist and abduction of thumb with fingers slightly flexed can be achieved. The device can be applied for the stimulation of all other

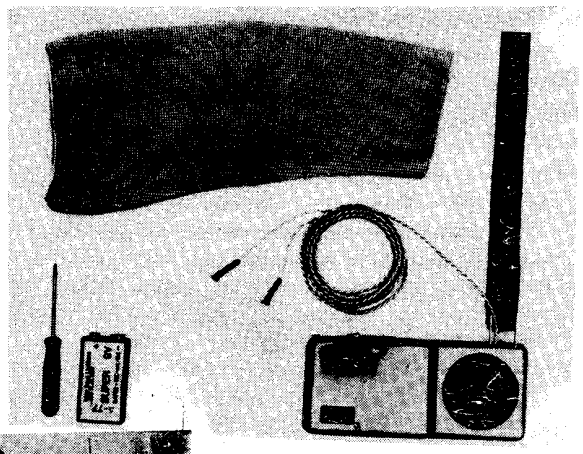

Fig. 3

Hand prehension stimulator FESE–H3 with position transducer strap, electrodes and elastic sleeve for their fixation. Screwdriver adjustments for frequency, pulse width and stimulation threshold are under the round black cover

Fig. 4

Hand prehension stimulator FESE–H3 applied for functional proportional stimulation of hand opening

muscles, where proportionally controlled pulse trains or cyclical on–off pulse trains are required.

Hand prehension stimulator FESE-H3 has two modes of operation – functional and therapeutic. In the therapeutic mode, patients have no control over the occurrence of stimulation. It is triggered cyclically every 6 seconds for a 3 second duration. Patients can only choose the amplitude of stimulation pulse trains.

In the functional mode intended primarily for hand opening a nonlinear characteristic enables proportional control of stimulated movement (7). In this mode, the stimulator is attached to patient's belt with the strap of position transducer over his shoulder (Fig. 4). To simplify use, the position transducer which converts mechanical displacement into electrical control signal has been incorporated into the stimulator itself. By moving the

shoulder up and down for 15 mm, the control of stimulation between preset threshold voltage and chosen amplitude can be accomplished. Starting the control from where the movement starts on allows proportional relationship between lifting the shoulder and stimulated movement. To save battery, energy consuming part of the circuitry is turned on only at presence of the control signal.

Besides proportional control in the functional mode, patients only choose the highest stimulation voltage from threshold one to 120 volts and turn the stimulator on to the selected mode of operation. Other controls are protected by a cover on the front side and are not intended for patients (Fig. 3). Frequency of stimulation pulses between 20 and 50 Hz, pulse width between 0.1 and 0.7, and stimulation threshold voltage between 20 and 50 volts can be preset for each patient individually by the therapist.

The hand prehension stimulator FESE–H3 is powered by a single 9 volt transistor battery. Battery instalation as well as placement of the stimulator and control strap are designed to be performed by patients. With one hour's daily use, the battery should last approximately 50 days in functional mode of operation or approximately 20 days in cyclical mode.

Five preliminary version prototypes of hand prehension stimulator have been tested in clinical and non–clinical environment for five years. One of them has been and is still used permanently by the same patient for four years. After thirty months, position transducer and intensity potentiometer were replaced at routine check. The present version has been tested also in clinical and non-clinical environment for two years. Besides permanent problems of all cutaneous stimulators with electrode cables, few malfunctions have been noticed from the part of electronics. Some problems have been noticed when the control strap has not been adjusted properly or when the stimulator has not been fastened enough to the body.

Therapeutic stimulator PLS–4

Therapeutic stimulator PLS–4 (Fig. 5) is forth improved version of previous therapeutic electronic devices for patients with peripheral and upper motor neurone lesions. It is intended for home use by patients themselves with the aim to intensify electrical therapy and to lessen to some extent the need for hospitalisation. It can be applied for electrical stimulation of nearly all superficial muscle groups.

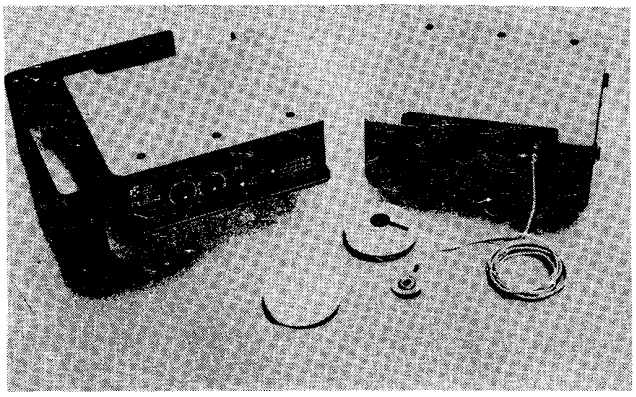

Fig. 5

Therapeutic stimulators PLS–4. Right: front panel with stimulation intensity control, on-off switch and electrodes. Left: uncovered rear panel with controls for the therapist

Due to the use of this powerful device by patients themselves, it has to be electrically absolutely safe and simply controlled. Safety has been achieved by independent battery powering, limited current capability of DC/DC converter, quick low current output fuse and clear graphical representation of set output current amplitude (Fig. 5). Linear slide potentiometer with large graphical symbol allows amplitude settings from 0 to 30 mA. Besides stimulation amplitude control, only on—off switch has been left to patients. All other control are situated on the rear panel which can be reached only after detaching rear cover fastened to the stimulator by two coin screws (Fig. 5).

Controls for the therapist on the rear panel allow setting of eight different stimulation modes with wide adjustments of their parameters:

- rectangular long "peripheral" pulses of current from 0 to 30 mA with repetition frequency from 0.1 to 1 Hz and pulse duration from 15 to 150 ms,
- exponential "peripheral" pulses with the same frequency and pulse duration having rise and fall times of 15 ms,
- hand triggering of single rectangular "peripheral" pulses with duration from 15 to 150ms,
- hand triggering of single exponential "peripheral" pulses with the same duration and shape,
- rectangular trains of thetanical current pulses from 0 to 30 mA with repetition frequency from 8 to 80 Hz and pulse duration from 0.15 to 1.5 ms; the ratio between stimulation and pause is 1 : 1, the duration of stimulation train changes proportionally to stimulation frequency and is approximately 2 sec. at 40 Hz (optionally duration can be divided or multiplied by 2),
- exponentially modulated trains of thetanical current pulses with the same parameter values having rise and fall times approximately 200 ms,
- hand triggering of single rectangular trains of thetanical current pulses with the above mentioned parameter values having duration of approximately 3 sec,
- hand triggering of single exponentially modulated trains of thetanical current pulses with the same parameter values.

The therapeutic stimulator PLS—4 is powered by battery pack consisted of four regular 1.5 volt "D" cells. Battery instalation can be performed by patients themselves. Four low cost zinc carbon cells offer approximately 50 hours of stimulation. With alkaline cells this time is considerably longer. The stimulator is equiped with a plug for optional accumulator pack and recharging unit.

With the electrical stimulation, acoustic feedback signal have been included. It lasts during the whole train of thetanic pulses or during the single "peripheral" pulse. Acoustic feedback should help strengthening volitional control of movements which should be added to the stimulation by patients.

The same as with underknee peroneal stimulator FESE—L2 and hand prehension stimulator FESE—H3, with therapeutic stimulator PLS—4, CMOS integrated technology and two sided printed circuits with metalised holes have been used to increase reliability. Since electromechanical components represent the most frequent source of malfunctions of electronic devices, only high quality components have been carefully selected. For eight different modes of operation, the need of a number of switches have been solved electronically by bilateral CMOS elements. They are controlled by a single high quality rotary switch through CMOS logic precoder. Thus the improved reliability and simple choosing of the desired mode have been achieved.

Through approximately 6000 hours of stimulation, only a few malfunctions have arised, none of them due to electronics. In past two years, 25 devices have been built and applied successfully partly as clinic devices in departments for physical therapy, partly

at patients homes, some of them at patients' beds in acute phase of lesion.

Fig. 6

Home use of the therapeutic stimulator PLS–4 preset for each patient individually by the therapist should lessen the need for hospitalization

Conclusion

With described stimulators designed for personal use by patients themselves, more successful application of functional and therapeutic electrical stimulation is expected. Taking in account the results of recent research studies and clinical praxis, some new features have been added in comparison with other orthotic and therapeutic stimulators. Controls for patients have been reduced and simplified and electronic circuitries have also been minimized. Usually more or less neglected aesthetical part of the design has been considered of elementary importance.

Further work should proceed in the direction of simplification and minimization of functional stimulators. To reduce even more, the only control for patients of underknee peroneal stimulator could be replaced by automatic amplitude sétting and resetting and also on–off switches might be abandoned with other stimulators. Besides, reliable cutaneous electrodes which need not to be replaced daily and should retain their conductive properties through their whole placement period have not been accomplished yet although some success with silver tape electrodes have been achieved. Where the lack of therapeutic effects implies permanent orthotic use of functional stimulation, implanted electrodes should be taken in consideration.

To evoke the therapeutic effects, new control signals should be studied rather than just mechanical triggering of the stimulation by now already classical heel switch at peroneal and multichannel stimulators for improvement of paretic gait or evoking new pattern of proportionally controlled hand stimulation in the cortex. Presumption that reestablishing a pattern in the cortex which once already existed should lead to the studies of more conscious control signals. They should be applied to therapeutic stimulators in the early stage of rehabilitation as well as to functional stimulators later on.

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