Selective Stimulation of the Common Peroneal Nerve for Hemiplegia: Long-Term Clinical Follow-up

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Abstract

We present the results of seven-year clinical follow-up in correction of drop-foot in one of three hemiplegic patients with Implantable Gait Corrector (IGC) for stimulation of the common peroneal nerve (CPN). Selective stimulation of muscles tibialis anterior (TA) and the peroneus brevis (PB) that contribute to strong dorsal flexion and moderate eversion of the foot was achieved with a monopolar half-cuff (cuff) installed on the nerve behind the lateral head of the fibula. Results show that a selective and gradual recruitment of fibres within the CPN innervating aforementioned muscles was achieved. This could be attributed to the current, charge balanced, and biphasic stimuli with a rectangular cathodic, and exponential decaying anodic component delayed for 50µs which were employed for stimulation. Results of gait analysis demonstrate significant improvements of gait without excessive eversion. They also show that the velocity of natural gait, cadence and stride length were significantly increased. However, the natural gait of the patient was still slower than in healthy individual. Results also show that the dorsal/plantar angular velocity of unstimulated foot could be estimated as higher than the angular velocity of stimulated foot. Electrophysiological findings have not revealed any reliable sign which could be attributed to the damage of the CPN induced by the cuff or by the stimuli applied for seven years. Namely, motor conduction velocity of the CPN remained almost unchanged for whole period of the time.

Key words: Common peroneal nerve, gait analysis, motor unit, nerve conduction, nerve cuff, selective stimulation.

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FES of the CPN to correct the gait has been shown to be a potentially useful means for the restoration of functional movement in the lower extremities of hemiplegic individuals [7]. The stimulation is applied during the swing phase of the affected leg dorsiflexing the foot and preventing its equinovarus position so that patients walk faster and more steadily. Raising the affected foot, the patient releases the heel switch that turns the external unit of the implantable system on, thus transmitting the signal to the implant and the nerve via the antenna. Stimulation is turned off by closing the switch at the beginning of the stance phase [15, 22]. Our main goal was to evaluate an IGC with a cuff for selective stimulation of the superficial region of the CPN innervating mostly the TA and partly one of the peroneus muscles [10, 14, 16, 17, 18]. Physiologically, larger motor units are activated after smaller ones have been recruited [5, 9, 13,]. Accordingly, selective stimulation of small groups of fibres within the motor nerve in the physiological order of recruitment is a desirable and important advantage of FES. However, conventional stimulation of motor nerves excites larger motor units before smaller ones [2] resulting in poor force gradation and rapid muscle fatigue. Therefore, the main goal was to change the frequently used stimulating scheme using capacitively coupled biphasic pulses by the scheme where the time delay of 50µs between the cathodic and anodic phase of the pulse pair was introduced. It was expected that a more gradual recruitment of the nerve fibres during selective stimulation of superficial region of the CPN could be obtained [3, 6]. A difficulty observed in previous works with direct nerve stimulation is that the difference in current level between threshold excitation and maximal recruitment is not large [3, 6, 12]. A more gradual recruitment of nerve fibres can be obtained if it is possible to increase the difference in threshold between different diameter nerve fibres. One possibility is to introduce a time delay between the cathodic and the anodic phase of the stimulating pulse. Namely, it was found that the presence of the anodic phase of the biphasic pulse could be used to abolish excitation initiated by the cathodic phase [6]. Since this ability has a fibre diameter dependence, it may be useful in separating the threshold levels of different diameter nerve fibres. During cathodic phase thick and thin nerve fibres in the vicinity of the stimulating electrode are activated. The conduction velocity of thick fibres is higher that that of thin ones, and, accordingly they are able to leave the excited territory before the anodic phase occurs. However, action potentials of thin fibres are not able to leave the excited region before anodic phase occurs so they could be quenched. Therefore, we introduced the delay of 50μs between phases to prevent quenching, and thus, to elicit some reduction in the slope of the recruitment curve. Besides, we proposed a relatively short cathodic phase with higher amplitudes, to additionally decrease the slope of the recruitment curve. Finally, the stimuli used in the evaluation of the system were current, charge balanced, and biphasic pulses with a rectangular cathodic component, and exponential decay anodic component delayed for 50μs [1, 3, 6].

Materials and Methods

The cuff with a monopolar electrode was constructed taking into consideration results of modelling selective stimulation of superficial regions and fibres with different diameters in the peripheral nerve and evaluated electric field generated within the nerve by the monopolar stimulating electrode [8, 11, 19, 20]. For the purpose of manufacturing the cuff two pieces of 0.1mm thick flexible silicone sheets were used. In the centre of either sheet a single rectangular electrode with a width of 2.5mm and length of 4mm made of 0.3mm thick platinum ribbon (99.99% purity) was mounted and mechanically connected to the insulated lead wires. Then, the silicone adhesive was deposited on the remaining sheet while the sheet with the electrode was placed on top of the adhesive thus forming the composite. After that the composite was compressed to a constant thickness of 0.3mm except at the area where the electrode was placed. Finally, the composite was insulated on both sides with thin Teflon sheet and rolled on the 3.5mm thick stainless-steel metal bar. When the adhesive reaction was completed the stainless-steel bar was pulled out and the composite opened. The completed cuff with an inner diameter of 3.5mm was then trimmed to a length of 18mm as presented in Fig.1a. Furthermore, both edges of the cuff were cut until the cuff with dimensions appropriate to fit the nerve trunk with dimensions within the desired range was obtained. The bulk body of a surgically implantable unit also presented in Fig. 1a was a 9mm high square body with dimensions of 22X22mm. Packaging the thick hybrid electronic circuitry and connection to the stimulating electrode involved the utilization of the unique properties of several biomedical materials. The use of these materials was necessitated by the constraints imposed by the stimulator electronics including: non-metallic encapsulation due to RF coupling and long service life after implantation. Accordingly, the thick hybrid electronic circuitry printed on both sides of the ceramic rectangular substrate was designed in a way enabling for sensitive contacts which are situated only on one printed side to be hermetically covered by a ceramic cover. Obtained single-side hermetically encapsulated hybrid electronic circuitry and receiving antenna was then enclosed in low ceramic pot with cover made of the same material. Finally, the dimensions of the implant body were determined by molding the aforementioned disc-shaped ceramic composition in medical grade silicone using custom designed tool in vacuum unit. A neutral electrode was made of platinum ribbon with a geometric surface of about 100mm^2 and was situated on one side of the body to be form part of its surface. The leads to the electrode exits the implant body on one of four sides through the reinforced feedthrough as also presented in Fig.1a.

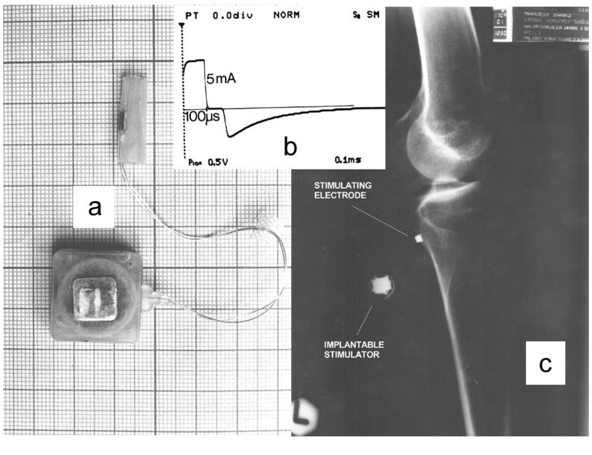

Figure 1. a) Implantable stimulator with half-cuff, b) Current, biphasic, pulse pair (stimulating part with an amplitude of 5mA and width of 100μs, and anodic exponential decaying part delayed for 50μs measured in saline solution (0.9% NaCl), and c) X-ray of the implanted stimulator with half-cuff showing its position on the common peroneal nerve.

In all three patients the CPN was exposed for a length of about 3cm. Then, the cuff was installed on the nerve behind the lateral head of the fibula as shown in Fig. 1c. A section of the nerve trunk between the two edges of the cuff was left uncovered. The final position of the cuff was determined by its slight movement in both longitudinal directions and by rotating it around the nerve, until strong dorsal flexion with moderate eversion was obtained. To activate mainly the TA in a possible selective way the stimuli presented in Fig. 1b had to be delivered to the electrode close to the superficial region in the deep peroneal nerve branch. To ensure optimal movement during implantation, the amplitude and pulse width of the cathodic component were varied while the repetition rate and the delay were preset at 20 pulses per second and 50μs, respectively. The IGC presented in Fig. 2 is a device, part of which is worn externally and part implanted.

It consists of three units: an external stimulator with antenna that generates and transmits radio-frequency signals with a carrier frequency of 2 MHz through the skin to the implant assembly presented in Fig. 2a; a heel switch which triggers the stimulator synchronously with the swing phase presented in Fig. 2b; and a surgically implanted unit consisting of a passive receiver which receives the signal from the external stimulator and converts it into a train of electrical pulses delivered to the electrode within the cuff presented in Fig. 1a. The output current of the rectangular stimulating cathodic component presented in Fig. 1b is adjustable from 1 to 10mA using the trimmer potentiometer situated within the external unit. The width of the aforementioned component could be set using the dial accessible to the patient as shown in Fig. 2c while the stimulation frequency was preset within the external unit and was adjustable from 20 to 33Hz. Similarly, the delay of 50μs was preset within the implanted unit. In the patient, correction of drop foot by using implanted stimulator started 10 to 14 days after surgery while the first gait analysis was performed from 4 to 6 months after surgery. However, after the time period of seven years the gait dynamics and EMG response of the TA and soleus muscle (SOL) with and without stimulation were determined. Since recording of EMG response from PB was difficult when using surface recording electrodes recording of EMG response from SOL was performed. Moreover, dorsal/plantar angular velocity representing contraction velocity of the tibialis anterior muscle was estimated from ankle goniograms for both, the unstimulated unimpaired ankle without, and the stimulated impaired one ankle with stimulation.

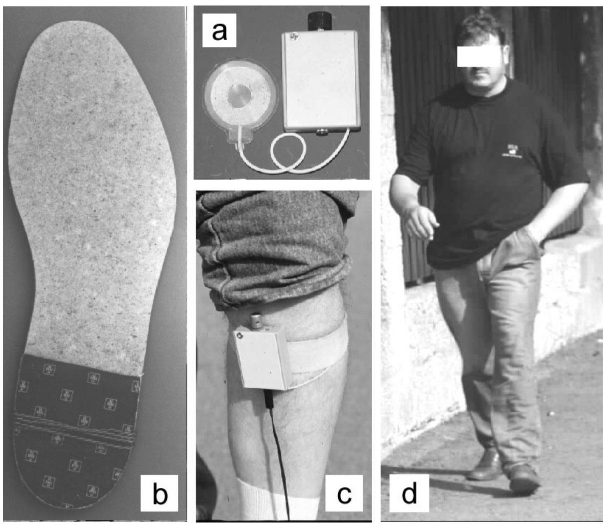

Figure 2. External parts of implantable Gait Corrector (IGC): a) external stimulator, b) heel switch, c) external unit attached on the leg of the patient, and d) gait of the patient with stimulation.

Results

In this paper we demonstrate the results obtained by gait analysis in one of three patients with IGC presented in Fig. 2d. The patient is daily using the IGC due to the foot-drop during the swing phase of the left lower leg. The basic deficits of his gait, when the stimulation of the CPN was not applied, were identified with the kinematic and kinetic analysis which was performed by a three dimensional measuring system (Vicon – Oxford Metrics Ltd.) and with the analysis of surface recorded EMG activities in some muscles (Myosyst 2000, Noraxon). Kinematic measurement and analysis included basic temporal and spatial parameters of gait. Basic results of this analysis are presented in Fig.3.

The influence of stimulation on stride length, speed, and cadence is presented in Fig. 3a in the way used by Grieve (1986) [4], and Winter (1991) [23]. Stride length and gait speed are given in statures and statures/s respectively, i. e. they are normalized to the person's height. For comparison with the natural gait of adult normal persons, a circled area with letters m for males and f for females is also given (Winter 1991) [23].

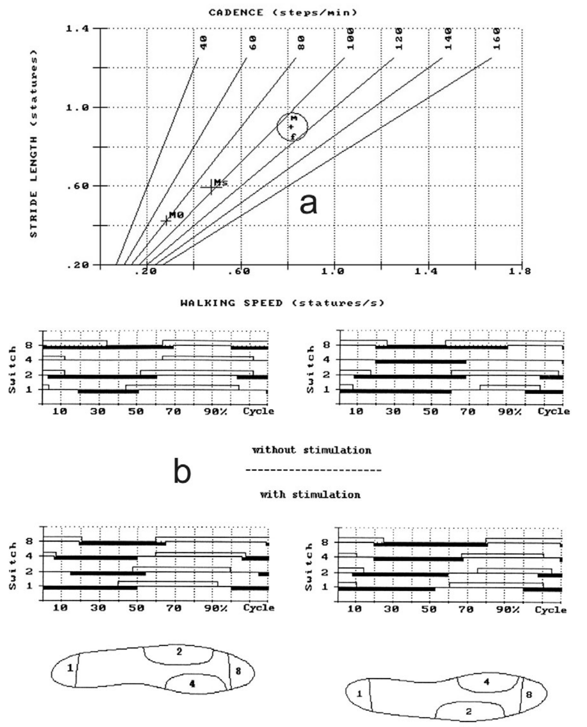

Figure 3. a) Velocity, cadence and stride length for the patients without (A, B), and with (As, Bs) stimulation. In circled area: natural gait of adult normal males (m), and adult normal females (f), b) Foot/floor contact patterns for a hemiplegic patient with and without stimulation.

Generally, the results showed that the speed of stimulated gait significantly increased by increasing stride length and cadence. Correction of foot contact and loading by stimulation is shown in Fig. 3b. The measured person wore special footware with sole switches as indicated in the outline of soles in the figure. In the outline foot-switch positions and their numerical indices are given to enable interpretation of the patterns. Switch/time diagrams give average durations of loading of separate foot-switches. Foot contacts with the ground are represented by full bars, and contacts for the contralateral foot with blank ones. Clearly expressed drop foot and equinovarus gait can be seen on the affected side for gait without stimulation. This deficit is well corrected with the application of stimulation. It seems that the inversion was slightly over-corrected. However, when stimulation was turned off, the foot returned to an inversion again. Step parameters: step, stance, swing, and double support durations, and step length were also analysed for unstimulated and stimulated gait. Besides a normal shift of the values towards those characteristic for an unimpared slow gait, better symmetry is found between the parameters of both sides with stimulated gait. With unstimulated gait an outstanding difference is observed for swing phases. They are very short for the unimpaired side. This can be explained by the fact that these intervals correspond to single support phases of the impaired side. Furthermore, double support phases, especially those belonging to weight acceptance on the impaired side, are unusually long. With stimulation gait became more steady, and symmetry of swing (single support phases) and double support phases improved the most. Ankle goniograms in sagital plane further illustrate the deficit in dorsal flexion during swing phase on the impaired side (Fig. 4a).

Kinetic analysis of ankle joint torque in sagital plane (Fig. 4c) shows a small plantar torque because initial contact is toe contact instead of normal heel contact with resulting dorsal torque. It is clearly seen that plantar push-off torque is also absent what results in diminished speed of gait. Primary reason for changed torque in the ankle are abnormal muscular activities of plantar an dorsal flexors. In Fig. 4b EMG activities of

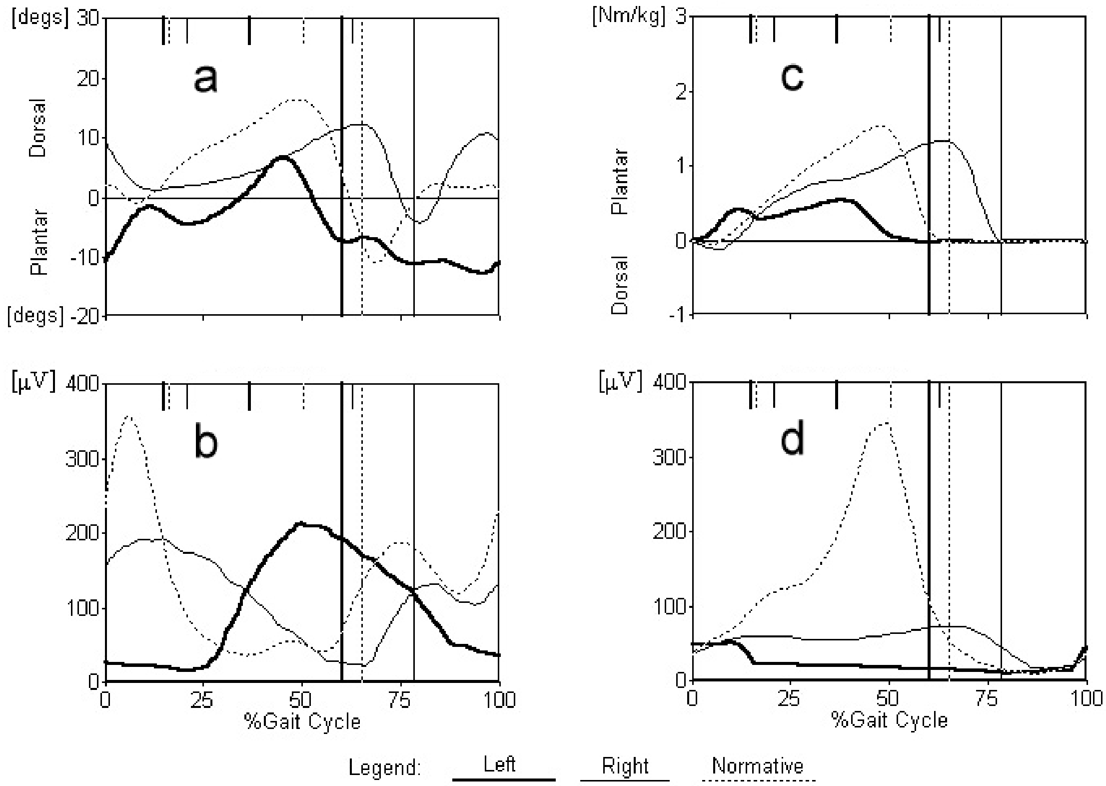

Figure 4. Elements of gait analysis used in evaluation of non-stimulated gait. a) goniogram of the impaired (left) ankle (thick solid curve), goniogram of the normal (right) ankle (thin solid curve), normative (dotted curve), b) EMG of the tibialis anterior muscle in the impaired (left) ankle (thick solid curve), EMG of the tibialis anterior muscle in normal (right) ankle (thin solid curve), normative (dotted curve), c) torque in the ankle during flexion of impaired (left) lower leg (thick solid curve), torque in the ankle during flexion of normal (right) lower leg (thin solid curve), normative (dotted curve), d) EMG of the muscle soleus in impaired (left) lower leg (thick solid curve), EMG of the muscle soleus in normal (right) lower leg (thin solid curve), normative (dotted curve).

the TA for the impaired left side (thick solid curve), for the contralateral normal side (thin solid curve) and normative (dotted curve) for that muscle are shown, and in Fig. 4d activities for the SOL. SOL activity explains small plantarflexion moment at toe contact and its later inactivity the lack of plantarlexion moment at push-off. Electrical stimulation of the CPN in the way described above, changes kinematics and kinetics of the ankle. In Fig. 5a goniograms of the impaired ankle without stimulation (thin solid curve), with stimulation (thick solid curve), and normative (dotted curve) are shown, while Fig. 5b shows EMG of the unstimulated TA, of the stimulated one, and normative EMG.

All EMGs are presented as averaged envelopes of several gait cycles. Since stimulation is turned on at slightly different instants of gait cycles, averaging yields rising and falling edges in the presented EMG signal. The aforementioned over-correction with stimulation is also clearly seen from the goniogram in Fig, 5a.

Kinematic, kinetic and EMG diagrams in Figs. 4 and 5 are shown in a slightly adapted way used by Vicon, being widely accepted standard for presentation of gait analysis results. Gait cycle is divided into stance and swing phase by full scale vertical lines, while short ticks on the top frame line represent contralateral foot-off, and foot-on events.

Results of electrophysiological measurements showed no sign of a damage induced by the cuff or by the stimuli to the CPN. Namely, there was no pathological spontaneous activity which could be recorded in the tibialis anterior and in the peroneus longus muscle by the method of needle electromyography. Besides, motor conduction velocity of the peroneal nerve remained almost unchanged for whole period of the time. A value of the conduction velocity mesured at February 2nd, 1993 was 55m/s while nine years later, measured at December 12th, 2000 it was 52m/s.

Discussion

This paper presents the preliminary evalutaion results of an IGC with a cuff for selective stimulation of fibres within certain superficial regions of the human CPN. It was shown that the stimulation system is capable of making a long-term selective activation, mainly of those muscles that contribute to strong dorsal flexion and moderate eversion of the hemiplegic's foot. The results obtained by gait analysis showed that the velocity of natural gait is significantly increased. The method of increasing velocity is similar to that in healthy individuals, by increasing cadence and stride length. It was also shown that increased velocity of gait and, at the same time, improved symmetry of the swing phase were obtained by improvement of all temporal and length parameters of the left and right steps. However, the gait of all patients was still slower than in healthy individuals. From recordings of EMG activity recorded on the surface of the TA, peroneus longus muscle (PL) and SOL it was observed that without stimulation there was no normal EMG activity of the flexor (TA) and extensor (SOL) while EMG activity of the PL could be considered as normal. However, with selective stimulation of the CPN both EMG activity of the TA and PL could be observed. Confirming our aim to elicit more gradual recruitment of nerve fibres by introducing a time delay of 50μs between pulse phases, it was noticed that contraction velocity of the TA in unstimulated foot is lower than contraction velocity of the aforementioned muscle in unstimulated foot. Namely, we believe that activation of strong skeletal muscles in as much as possible a physiological manner is required mainly to reduce fatigue and preserve the natural dynamic load of joints that can arise when the muscle is activated in reversed order of recruitment [8]. We also believe that the results obtained represent an important contribution to research oriented towards rehabilitation of paralyzed individuals with implantable stimulators for selective stimulation of peripheral nerves. Nevertheless, the results are important for the population of hemiplegic patients, enabling them to use a relatively simple and reliable system for correction of drop-foot. Therefore, we believe that we have succeeded in our goal to develop a simple implantable gait stimulation system eliciting reliable and reproducible force recruitment characteristics for the long time required. An IGC system requires a relatively simple procedure of implantation and is suitable for a wide population of patients without limitations concerning age. In spite of the fact that there is a very low risk during surgical implantation, some possibility of inappropriate functioning still remains. Fortunately,

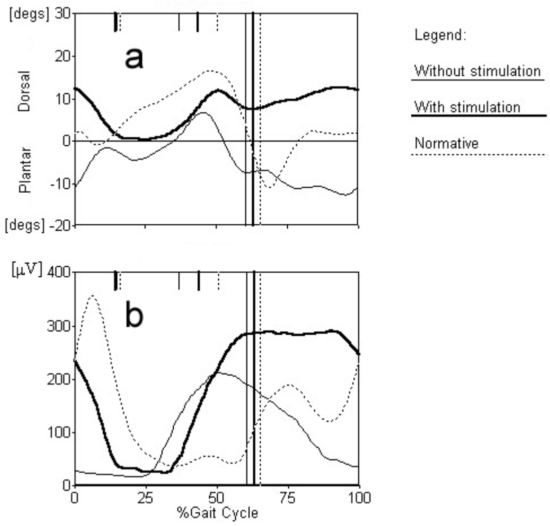

Figure 5. a) Goniograms of the impaired (left) ankle without stimulation (thin solid curve), with stimulation (thick solid curve), and normative (dotted curve), b) EMG of the unstimulated tibialis anterior muscle, of the stimulated one, and normative EMG.

there is also a simple surgical procedure in the case of removal or replacement of the implantable stimulator. In comparison to other similar systems developed elsewhere [22], our system enables highly selective stimulation mainly of those muscles that contribute to strong dorsal flexion and moderate eversion of the hemiplegic's foot. Namely, several groups of investigators have developed different implantable devices, but in most cases their use has been abandoned, mostly due to inadequate functional movement obtained in a certain period of time after implantation, which was elicited by electrodes enabling low selective stimulation. Finally, the results of initial evaluations also showed that there was no sign of an adverse effect of the cuff concerning the occurrence of neuropathy. Of course, further experience will determine the ultimate usefulness of the described implantable system.

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