TWO CHANNEL IMPLANT - APPROACH TO AN ORTHOTIC DEVICE

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Summary

The investigations in the field of multichannel electrical stimulation showed that a possible and adequate solution should be found in implantable systems. From the gait pattern analysis the data for the programmed stimulation of the paralyzed muscle groups were derived. For the first experiment the activation of muscle groups controlled by tibial and fibular nerves was selected.

Anatomical and surgical conditions were considered when designing the implant geometry and radio frequency power unit.

The complete stimulation system includes several units: implantable r.f. stimulator, control unit with adjustable pulse generator, r.f. power unit, separate for each channel and a common programmable timing unit with the remote switch receiver and remote switch transmitter.

In recent times the functional electrical stimulation becomes more and more popular as a method in rehabilitation. Functional electronic peroneal brace FEPB is an orthotic device based on functional electrical stimulation. The study and evaluation of the patients using FEPB (Ljubljana Functional Electronic Peroneal Brace with surface and implant electrodes) showed us also the therapeutic effect of functional electrical stimulation. It is evident from clinical observation, that the functional electrical stimulation has a time prolonged effect measurable in hours, days, or weeks /9/. The success of the treatment depends upon regular use, which again depends upon the simplicity of the application. Today we have two types of electronic braces; one with electrodes /2/ which must be attached to the skin at proper points every day, and one with implanted electrodes /4/. The proper location of implant electrodes is made during the surgical procedure /4/. This is the main reason why the patients who used both systems prefer the implant version, which also avoids the need for electrode wires and improves the cosmesis of the system /5/.

The investigations of A. Kralj in the field of multichannel electrical stimulation based on the study of muscle groups activity coordination for one, two, and three joints of the leg during the walk

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confirmed the importance of further development of implant technics for progress in orthotics as well as in therapy /6, 7/.

After three years of experimental work and careful evaluation of the single channel implant in hemiplegic patients /3/, we decided to try a two-channel implant system. Agonistic and antagonistic control of the ankle joint was selected for several reasons:

(1) We wanted to change the gating of existing peroneal brace regarding the natural gating, expecting an improved walking stability and therapeutic effect;

(2) The study of the influence of the neural mechanisms on the spinal level involved in the functional control of agonistic and antagonistic muscle groups on the functional electrical control of the ankle joint was of interest;

(3) We would use the existing implant channel controlling nervus fibularis.

The phasic action of the existing electronic peroneal brace is based on a triggering reference signal derived from the heel switch which is activated at the moment the heel is lifted. At the same time the peroneal nerve is activated by a stimulating pulse train. In this way the complete push-off phase is replaced by dorsal flexion (Fig. 1) which makes the appearance of the patient's walk still abnormal in spite of the functional improvement.

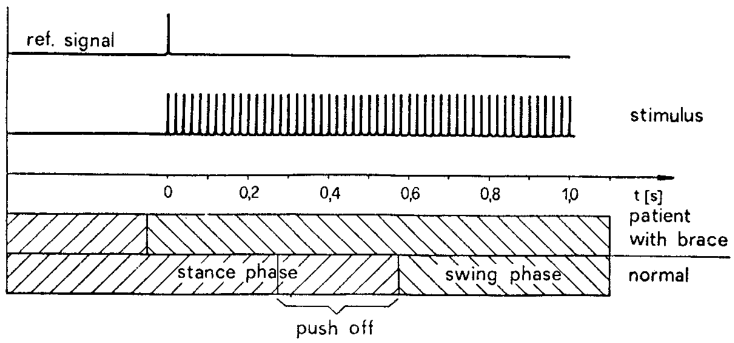


Fig. 1. Timing diagram for peroneal brace

By use of a two-channel implant system we are able to introduce the activation of muscle groups responsible for push-off - m.gastrocnemius and m.soleus via n.tibialis. This implies the introduction of the proper time delay interval in the second channel controlling dorsal flexion and eversion via n.fibularis.

The corresponding timing of the two-channel stimulator in which channel I controls m.triceps surae (gastrocnemius and soleus) and channel II m.tibialis anterior and peroneal muscles is shown in Figure 2. The delay time interval can be determined as a delay between channel I and channel II or as a delay of channel II defined to the reference signal. The second solution was chosen because it allows also overlapping of both channels.

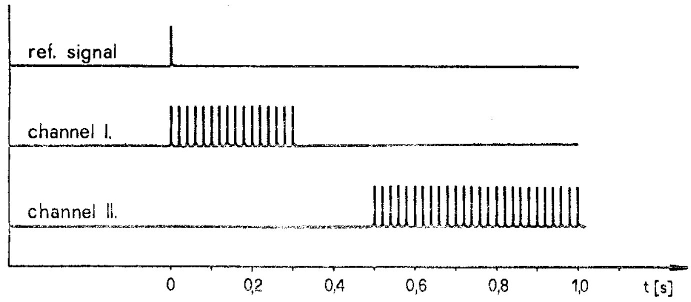


Fig. 2. Timing diagram for two-channel implant brace

The stimulator is triggered by the heel switch transmitter as in the standard peroneal implant stimulators (4). The block diagram of the electronics involved is shown in Figure 3.

The time delay adjustment is possible from 0 to 800 ms. In both channels the pulse frequency adjustment is in the range of 10 - 150 Hz and pulse duration from 0.04 - 1.2 ms. The train length adjustment is from 180 to 600 ms.

The difference in carrier frequency of both channels (1.7 and 1.1 MHz resp.) is 0.6 MHz to avoid intercoupling of both channels in the case both implant receiver stimulators are located close to each other. The implants are of the "Ljubljana Type" (4) (Fig. 4). This type of implant allows very small surgery to avoids the danger of electrode breakage.

The stimulators were implanted in the region of fossa poplitea as shown on the X-ray in Figure 5. The implantation was performed at the Surgical Clinics, University of Ljubljana in a left leg of a volunteer by E. Vavken and M. Benedik. Local anasthesia was used. The

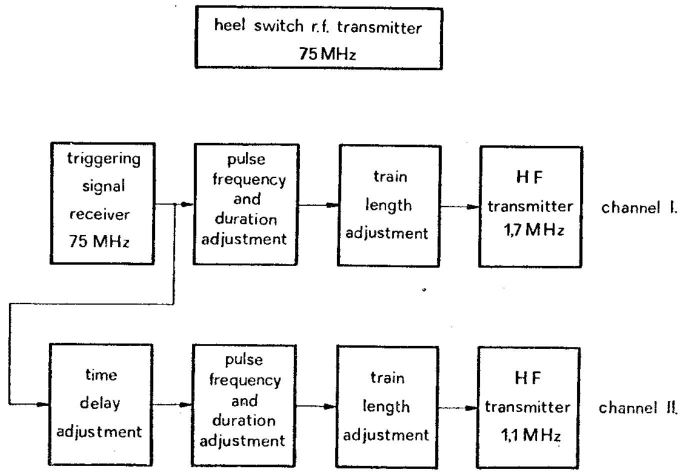


Fig. 3.

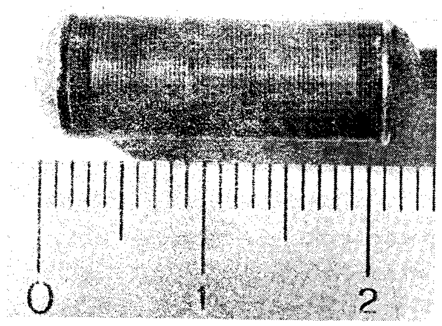


Fig. 4.

distance of both implants is 52 mm calculated from the X-rays in two projections. No electrical coupling was detected between the implants.

The effects of two channel implant stimulation were studied by measuring the moment about the ankle joint by means of a special brace. The results were registered on the two channel paper recorder and read out as in /%/. The first channel displays the train of the stimuli for both implants. The second channel displays moments in both directions corresponding to dorsal (down) and plantar (up) flexion. The results are shown on the graphs in Figures 6 - 10.

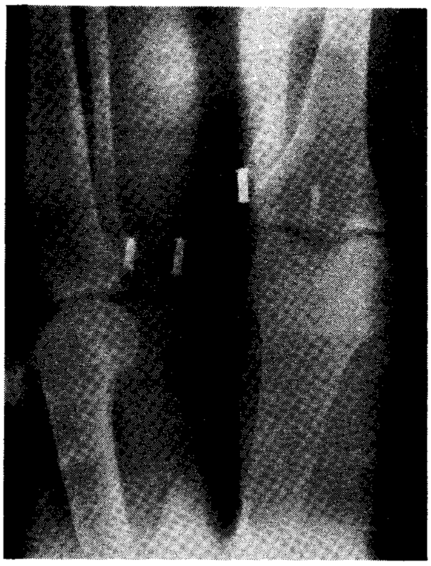


Fig. 5.

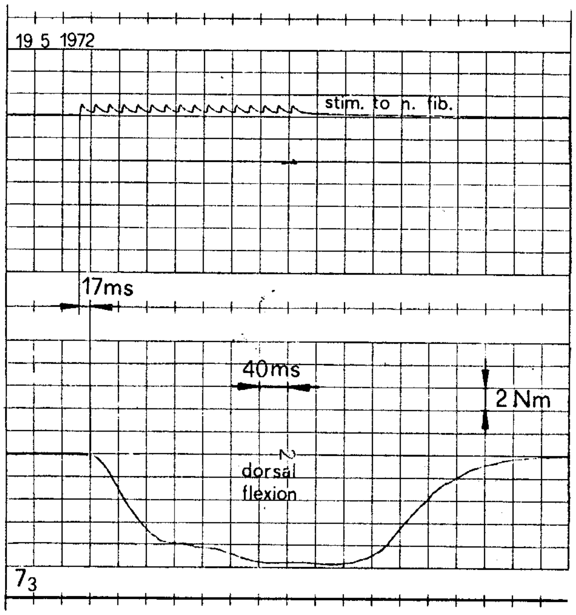


Fig. 6.

Figure 6 shows the answer to the separate stimulation by channel II - n.fibularis. By changing the stimulus parameters, amplitude, pulse duration, and frequency, certain combinations of dorsal flexion and eversion of the foot are achieved. Only the moment corresponding to the dorsal flexion is displayed. The time delay between the pulse train onset and the beginning of the rise of the force moment is 17 ms.

The separate stimulation of the channel I, m.triceps surae gives rise to very different types of functional responses, depending on the stimulus parameters and slight change of electrode position.

For channel I, considering the direction of the mechanical response (dorsal and plantar flexion), undirectional and bidirectional response can be distinguished. Whatever the interfereing mechanisms, it means activation of agonistic and antagonistic muscle groups by efferent or afferent excitation of agonist and afferent excitation of antagonist.

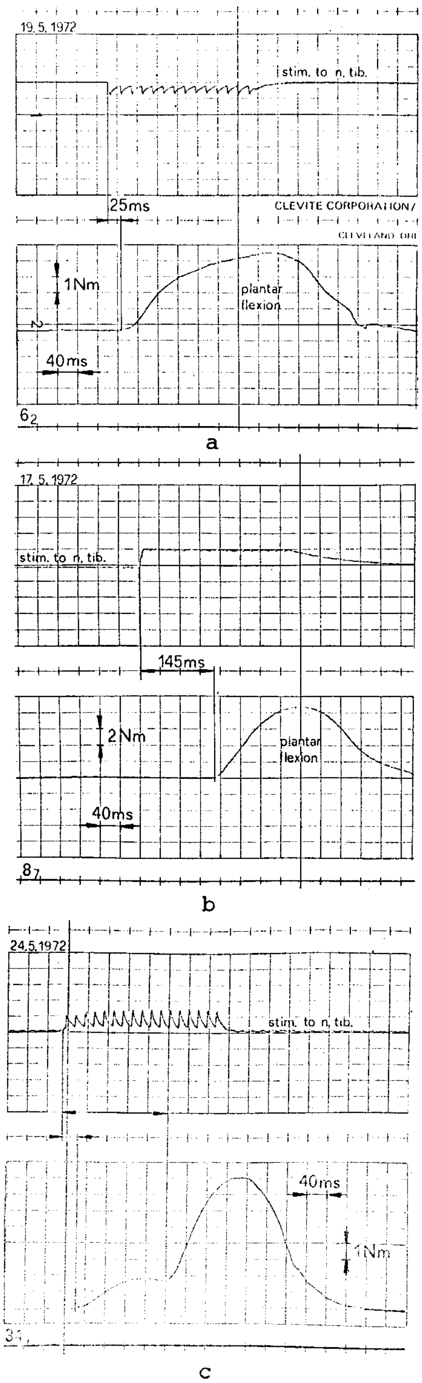
In the case of undirectional response several types were observed. On Figure 7a plantar flexion is delayed for 25 ms - type I. On Figure 7b plantar flexion is delayed by 145 ms. It was estimated that the type I is due to direct motor excitation and type II to afferent excitation of interneural mechanisms at spinal level. In the case of Figure 7c, both types were provoked.

Bidirectional response is shown on Figure 8. Plantar flexion is followed by dorsal flexion delayed for about 180 ms.

In Figure 9 the functional response of the antagonistic group is provoked in absence of the agonist response with a delay time of 116 ms.

In Figure 10 the response to activation of both channels is presented, corresponding to the timing shown in Figure 2. This is the answer which was desired in designing a two-channel implant brace.

Also the facilitation effect of channel I upon channel II was observed. The moment due to the response of m.tibialis anterior was 300% higher by amplitude if proceeded by activation of antagonistic group (Fig. 11). Even if the stimulus is too low to give rise to a mechanical response it can be provoked if preceeded with slight activation of the antagonist (channel I).



19.5.1972
stim. to n. tib.
25ms
CLEVITE CORPORATION/
1Nm
plantar flexion
40ms
a
17.5.1972
stim. to n. tib.
145ms
2Nm
plantar flexion
40ms
b
24.5.1972
stim. to n. tib.
40ms
1Nm
c

Fig. 7.

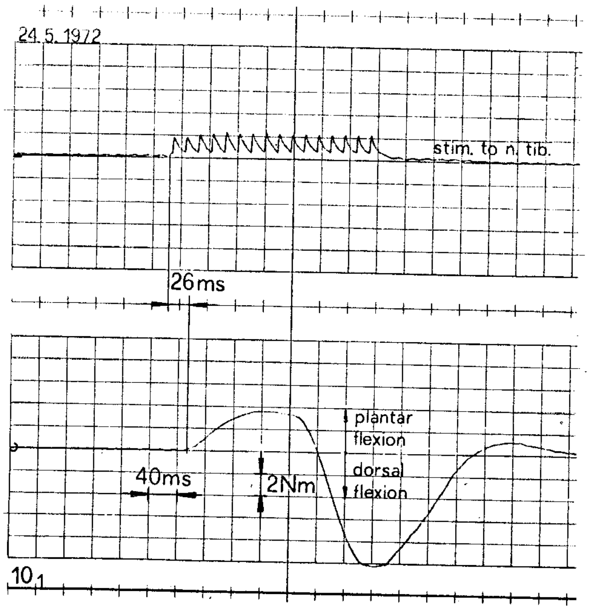

24.5.1972
stim. to n. tib.
26ms
plantar
flexion
dorsal
flexion
40ms
2Nm
10,1

Fig. 8.

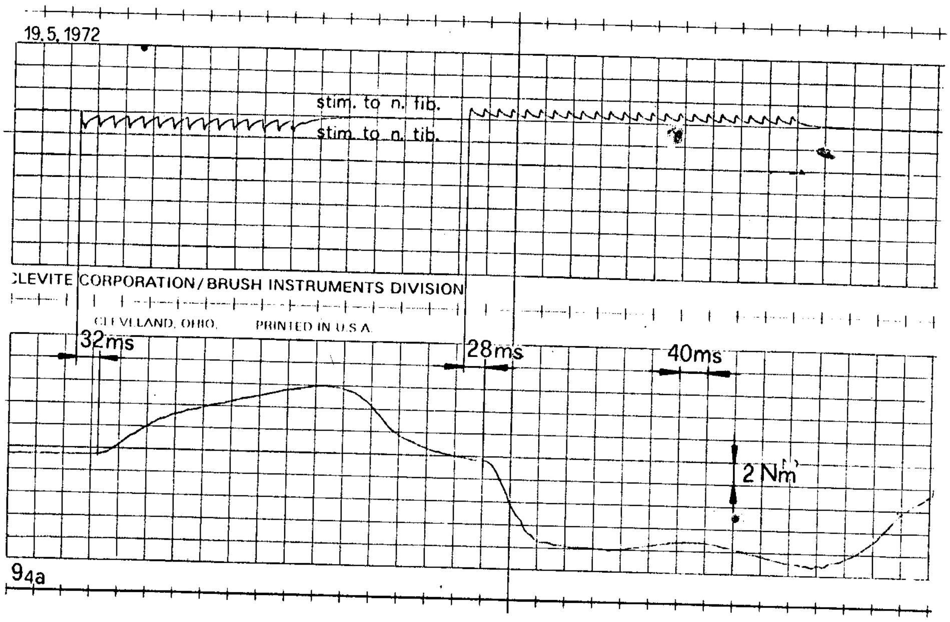

19.5.1972
stim. to n. tib.
stim. to n. tib.
CLEVITE CORPORATION/BRUSH INSTRUMENTS DIVISION
CLEVELAND, OHIO. PRINTED IN U.S.A.
32ms
28ms
40ms
2 Nm
94a

Fig. 10.

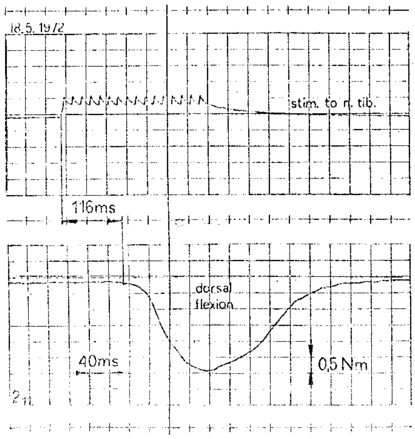


Fig. 9.

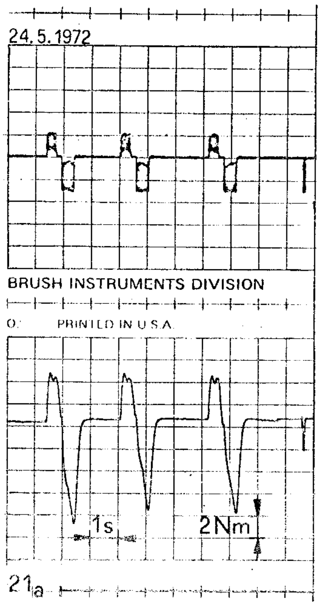


Fig. 11.

Conclusion

The functional response that means the integral effect of muscle fibers activated due to excitation of two antagonistic muscle groups was measured, in terms of Newton meters and ms. The activation of m.gastrocnemius and m.tibialis anterior was radio frequency controlled via two implanted stimulators. The desired functional response was always achieved by appropriate timing and stimulus parameters. In this case the facilitating effect of the proceeding activation of the antagonistic group (m.gastrocnemius) upon the tibialis anterior muscle was observed.

The role of different anatomical structures electrically activated in the described experiments should be investigated in patients before the practical use of results should be considered in design of orthotic devices.

Different types of responses to electrical excitation as described above confirm that practical use of neurophysiological mechanisms in functional electrical stimulation is possible. This should be proved by careful investigations in plegic patients and experiments controlled by conventional neurophysiological methods. It is also required for successful engineering design of two or more channel closed loop control systems. On the other side, the experimental work presented in this paper gives promise for practical realization of multichannel electrical stimulation.

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