Proceedings of the Eighth International Symposium on ECHE, 1984, Dubrovnik

CLINICAL EXPERIENCES OF FUNCTIONAL ELECTRICAL STIMULATION IN JAPAN

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ABSTRACT

History of functional electrical stimulation (FES) in Japan is shorter than that in Europe and United States, particularly in clinical application. However, in recent years, researchers who are interested in FES have increased remarkably in Japan. We developed a small peroneal stimulator with the objective of taking it out in the market. Using the stimulator, clinical factors of hemiplegia were analyzed relating to FES on 80 patients. It was found that hemiplegic patients who were in slight spasticity level and above stage IV of lower limb functional level were good candidates for using the stimulator. According to our experiences of using the stimulator for daily activities of patients, the peroneal stimulator was very suitable for Japanese life style. Furthermore, a C5 level quadriplegic patient was tested with the simplest hand stimulator using surface electrodes. It has been proven that C5 patient is able to restore his grasping by FES using surface electrodes with the aid of a splint.

INTRODUCTION

Until several years ago, in Japan, there were few researchers who were interested in functional electrical stimulation of locomotor system(FES) and few hospitals where FES was actually used for patients. Today, interest in FES has grown remarkably. This paper introduces the history and present status of FES in Japan and also our clinical experiences of FES for hemiplegia and quadriplegia.

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This study was supported in part by grant from the Rodo Fukushi Jigyodan.

HISTORY AND STATUS OF FES IN JAPAN

FES was first introduced in Japan by Prof. Kato, Waseda University, Tokyo in 1968. He translated the book entitled, " External Control of Human Extremities " into Japanese which contained papers concerning FES written by Reswick, Gracanin and others (6). However, most orthopedic surgeons and engineers in Japan during those days were more interested in powered prostheses related to the side effects of Thalidomide and showed little interest in paralysis itself and its functional treatment.

The first actual study on FES in Japan used implanted electrodes instead of surface electrodes. Imamura and others presented a paper entitled, " Stimulation of nerve innervating the paralysed muscle with implanted electric capsule " at the First Symposium on Biomechanism in 1970 in Japan (4). Sakai Medical Appliances Company in Tokyo during the same year applied for a patent on " Direct stimulator for paratic nerve using wireless system " (15). Tamaki (1971) and Yamane(1972) who worked previously at the Rancho Los Amigos Hospital introduced the application of clinical use of FES with implanted electrodes (17, 20). Takebe and others reported on clinical experiences in rehabilitation of hemiplegic in United States (16).

Haida and Negishi reported on the results of clinical test of a peroneal stimulator developed in Netherlands in 1975 (2). This was the first paper in Japan which reported on the use of FES with surface electrodes. Yamada and others presented results on gait analysis for hemiplegic patients with the same stimulator as Haida and Negishi at the 12th Annual Meeting of Japanese Physical Therapist Association in 1977 (19). Kakurai reviewed the reports concerning studies of FES made throughout the world in 1979 (5). However, until we began a new project to develop small peroneal stimulator with the objective of taking it out in the market in 1979, there were only few hospital in Japan where FES was actually used in the rehabilitation of hemiplegic patients (8, 9).

The Rehabilitation Engineering International Seminar-1982 (REIS-'82) was held in July 1982 in Tokyo, where FES was taken up as one of the main theme. Three papers concerning FES were presented which included papers by Vodovnik, Tamaki and Kawamura at the seminar (13). After that occasion, researchers who became interested in FES have increased remarkably in Japan. Recently, Handa and others are studing FES for upper-limb of quadriplegic patients using percutaneous electrodes (3). We are now trying to apply the FES using surface electrodes to the upper-limb of quadriplegic patients.

This January, a conference was held at the Osaka University as one of activities of the Japanese Society of Medical Electronics and Biological Engineering. At this conference, five papers were presented by Japanese researchers in cluding papers by Tamaki, Takebe, Handa and us.

DEVELOPMENT OF PERONEAL STIMULATOR AND ITS APPLICATION INTO JAPANESE LIFE STYLE

Although there are many papers written on peroneal stimulator since it was introduced by Liberson and others in 1961, only a few authors have described the relationship between its effectiveness and clinical factors of hemiplegia such as spasticity level and functional level with large patient population (11). Furthermore, there have been hardly any reports of practical value thus far on the peroneal stimulator concerning its use in daily activities by the Japanese people. We report here specification of our stimulator which was developed with the objective of taking it out in the market in Japan, an analysis of clinical factors in 80 hemiplegic patients in relation to the effectiveness of the stimulator and results of application of the stimulator to daily activities involving Japanese life style.

Peroneal Stimulator

The specification of our peroneal stimulator is shown in Table 1. The foot switch contains a tape switch element at the heel area and is inserted as an insole switch into the affected side of shoe. The two surface electrodes are made of conductive rubber and sponge pad which are moistened before use. The active electrode is 16 mm in diameter and placed the popliteal fossa, over the peroneal nerve with elastic strap. The indifferent electrode is 18 mm in diameter and placed somewhere on thigh or shank (Figure 1).

Table 1. SPECIFICATION OF THE PERONEAL STIMULATOR

Pulse form:	rectangular, negative
Pulse rate:	30 Herz
Pulse width:	0.3 ms
Raise time:	50-350 ms
Decline time:	150 ms
Max. Output:	160 V
Battery:	9 V dry cell
Dimension:	70x62x20 mm
Weight:	100 g

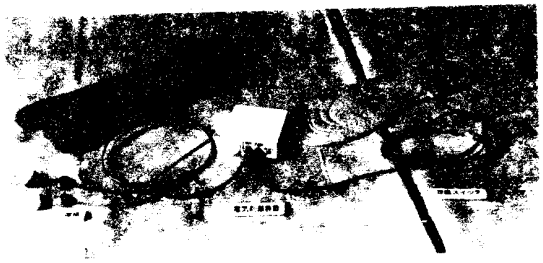

Figure 1. Complete set of peroneal stimulator

The stimulator will be brought in the market this spring after receiving approval of the Japanese Ministry of Welfare.

Analysis of Clinical Factors in Relation to FES

Analysis of clinical factors in relation to effectiveness of the stimulator was carried out on 80 hemiplegic patients at the Osaka Rosai Hospital and other hospitals in Japan. The criteria for patient selection were as follows:

1. Ability to walk without help or with one cane.
2. Insufficient voluntary dorsiflexion and/or eversion of the ankle joint during swing phase.
3. Complete range of motion of all joints of the lower-limb.

CHARACTERISTICS OF PATIENTS: Forty five of 80 patients were right hemiplegia and 62 out of 80, male. Their ages ranged between 24 and 81 years, averaging 56 years. Thirty of 80 patients were cases involving cerebral hemorhage; 27 patients, cerebral infarct; 21 patients, cerebral embolism and 2 patients, cerebral tumor. The time lapse after stroke were between 3 months and 3 years and 10 months, averaging 11 months. 29 of 80 patients could walk without help and remainder needed cane for walking.

All patients were evaluated on spasticity level and lower-limb functional level as clinical factors in relation to FES. Spasticity level of the planter flexors was evaluated according to the following clinical scale when standing:

Slight: Able to place the heel on the floor immediately.
Moderate: Able to place the heel on the floor after certain lapse of time.
Severe: Not able to place the heel on the floor till the end.

Lower-limb functional level was evaluated according to the following scale (Brunnstrom (1), Ueda and Fukuya (18)):

Stage I: No voluntary motion.
Stage II: Voluntary motion only by facilitation.
Stage III: Initiation of synergy.
Stage IV: Initiation of separation from synergy.
Stage V: More separation from synergy
Stage VI: Normal.

Forty six of 80 patients were in the slight spasticity level, 31 moderate and 3 severe. Twenty six of 80 patients were in stage III of lower-limb functional level, 29 in stage IV, 20 in satge V and 5 in stage VI.

RESULTS: All patients used the stimulator for 30 minutes or more per day during 2 weeks at our hospitals. Effectiveness of the stimulator was evaluated mainly relating to correction of insufficient dorsiflexion and eversion during swing phase after 2 weeks. That is, cases getting complete correction were evaluated as " effective " and cases getting imcomplete or no correction were evaluated as " not effective ".

Fifty two of 80 patients (65%) were classified as " effective " and remainder(35%) as " not effective ". Analyzing the relationship between effectiveness and clinical

factors, " effective " cases were found in 35 of 46 patients (76%) who were in slight spasticity level, 17 of 31 patients (55%) in moderate spasticity level and none (0%) in severe spasticity level (Figure 2). In connection with lower-limb functional level, patients found " effective " included all 5 patients in stage VI, 16 of 20 patients (80%) in stage V, 21 of 29 patients (72%) in stage IV and 10 of 26 patients (38%) in stage III (Figure 3).

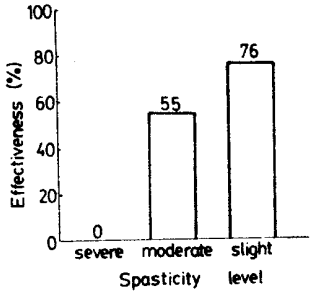

Figure 2.
Effectiveness of stimulator
--Comparison with spasticity--

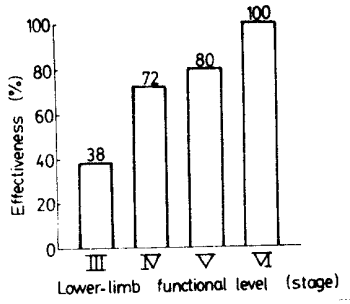

Figure 3.
Effectiveness of stimulator
--Comparison with functional level--

UTILITY OF FES IN JAPANESE LIFE STYLE

In order to study the practical value of the peroneal stimulator in activities of Japanese life style, four outpatients used the stimulator in their daily activities for one month or more. Two of four patients were female and their ages were between 30 and 66 years, averaging 48 years. Two of four patients were in stage IV of lower-limb functional level, remainder in stage V. Three of four patients were in stage VI of upper-limb functional level who could put on and off the stimulator theirselves. Only one patient was in stage IV of upper-limb functional level who could not wear it herself (Table 2).

Although the peroneal stimulator used for daily activities was the same as that used for analysis of clinical

Table 2. CHARACTERISTICS OF PATIENTS USING FES FOR THEIR DAILY ACTIVITIES AND ITS RESULTS

Cases	1	2	3	4
Age	48	30	48	66
Sex	female	female	male	male
Functional level of lower-limb	V	IV	V	IV
Functional level of upper-limb	VI	IV	VI	VI
Putting on & off FES by oneself	possible	impossib.	possible	possible
Number of days using FES weekly	4-6	2-3	7	6
Duration using FES per day (hours)	3	3	11-15	10
Places FES used mainly	home	home & shopping	home & own shop	home & walking

factors, only the foot switch was modified so that it could be used without shoes. The insole switch was cut at the front of heel area. Only the heel part of the switch was used under the heel and fixed by a supporter. The patient with the switch could walk anywhere with or without shoes.

All patients completed one month or more of regular usage of the stimulator. All of them accepted the use of stimulator. Three of the four patients used it almost every day of the week, but one patient who was stage IV in upper-limb functional level and could not put the stimulator herself, used it only two or three days per week. Male patients used it for 10 hours or more a day and used it mainly for outside walking, but female patients used it only for about three hours a day and used it mainly inside the house (Table 2).

Advantages that were mentioned by the patients were as follows:

1. Able to walk easily and safely on "tatami" floor (Figure 4).
2. Able to sit in Japanese style on "tatami" floor (Figure 5).
3. Able to crouch in using Japanese toilets.
4. Able to put on and off shoes readily (Figure 6).
5. Able to wear shoes of same size on both sides.

6. Able to wear shoes with any heel height.

Disadvantages mentioned by the patients were as follows:

1. Putting on electrodes were troublesome and time consuming.
2. Connection cords became an obstacle, particularly when sitting in Japanese style and also crouching.

Figure 4. Walking on "tatami" floor with FES

Figure 6. Putting on and off shoes

Figure 5. Sitting in Japanese style with FES

Discussion

Although there are many clinical factors related to

indication of peroneal stimulator for hemiplegic patients including range of motion of lower-limb joints, superficial and deep sensation, mental state, etc., spasticity level of lower-limb and lower-limb functional level mainly corelating to synergy of lower-limb are two of the most important factors. We investigated those factors in 80 hemiplegic patients. Summarizing the results, two thirds of hemiplegic patients who could walk without help or with one cane, were suited for the peroneal stimulator. Analyzing the clinical factors, the patients who were categorized in slight spasticity level and above stage IV of lower-limb functional level were good candidates for it.

Prior to discussion of the peroneal stimulator with relation to Japanese life style, we would like to describe briefly the unique life style of the Japanese people. Even though the Japanese people today wear shoes outside, the custom to take off shoes prevails when entering a home. Furthermore, the Japanese sits on "tatami(straw-matted)" floor in Japanese style sitting. Japanese style toilets necessitate crouching. In order to suit the above Japanese life style, there are special requirments for orthotic device to be used in Japan. In our limited experiences involving four patients, the peroneal stimulator was very useful for such Japanese life style by having the foot switch modified to adjust to the life style (7).

CLINICAL APPLICATION OF HAND STIMULATOR FOR QUADRIPLEGIA

Since Long and Masciarelli reported on "electro-physiologic splint" for quadriplegic patient in 1963 (10), there have been many papers on FES for them (12). Except for the paper by Rudel and others in 1981 (14), all authors have used percutaneous electrodes. However, skin penetration of percutaneous electrode may cause breaking of wire in the body and infection of the body. Those problems are still not solved completely. We are now studying FES for upper-limb in quadriplegic patient which use surface electrodes with the objective of putting it to practical use.

Patient Selection

A C5 level quadriplegic patient was chosen as one suited for FES use because of the following reason. C5 patient has sufficient control of shoulder and elbow flexion but lack grasping movement which makes his upper-limb useless. If FES provides functional prehension and release of the hand, he can grasp an object and bring it to the intended position. However, in the case of C4 patient who lack all joint movement of upper-limb, even if FES provides prehension movement, he can not reach an object as well as bring it to the intended position. In the case of C6 patient, he can grasp an object by tenodesis action even without FES.

The patient is 40 years old. He was involved in an industrial accident 3 years ago. He can control his shoulder and elbow joint, but can not control his hand. Before using of FES, he could eat his meal and write using self devices

and put an object between both hands.

Stimulator

The system that used for the patient is shown in Figure 7 and 8. Finger flexors and extensors of only right hand are stimulated through two pairs of surface electrodes by two channel stimulator. The stimulator is controlled by a toggle switch which is manipulated by his left hand. When the switch is in neutral position, none of the muscle is stimulated. When the switch is in either of the side position, one side of muscles is stimulated. Although the method of control is on/off control in this system, strength of stimulation is increased gradually at the start of stimulation so that finger movement is gradual. The frequency of the stimulator is 30 Herz; the pulse width, 0.3 ms; the rise time of stimulation , 80 ms; and the maximum output, 160 V. Each active electrode is placed on motor point of each muscle group.

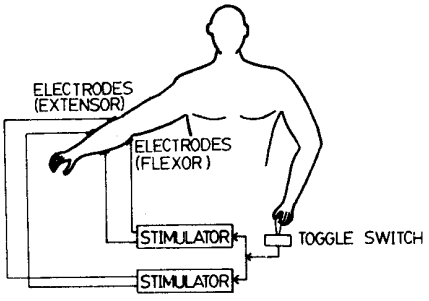

Figure 7.
Block diagram of system for hand stimulator

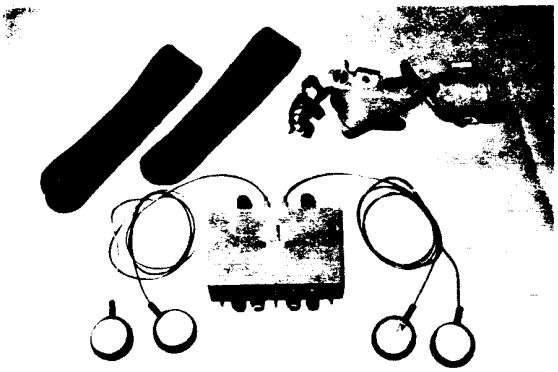

Figure 8.
Complete set of hand stimulator with a splint

Splint

In order to get active prehension and release only by

2 channel stimulation, a splint which stabilized the wrist and thumb in the functional position was used. Furthermore, four fingers, index finger to small finger, were held together by the finger support. The finger support allowed flexion and extension of the four fingers together at the MP joint, when flexors and extensors were stimulated. The Engen flexor hinge splint was modified for this purpose.

Results

The patient using the hand stimulator was able to pick up a small object by the method of three-jaw pinch and also hold a large object like a glass by the method of open-grasp prehension (Figure 9). After grasping the object, he could to bring it to the intended position using residual movement of his shoulder and elbow joints. Control of flexion and extension of fingers by manipulating the toggle switch was very easy. Although control feature of the stimulator was on on/off control, he was able to grasp and release the object without a hitch by gradual increase of stimulation strength. Maximum pinch force was 0.5 Kg which required about half a second after the start of stimulation.

The stimulator has been accepted by him and he is continuing to use it for eating, writing and other daily activities at the hospital. Disadvantages of it were difficulty of placing the electrodes, particularly in finding the motor point of finger flexors and insufficient pinch force.

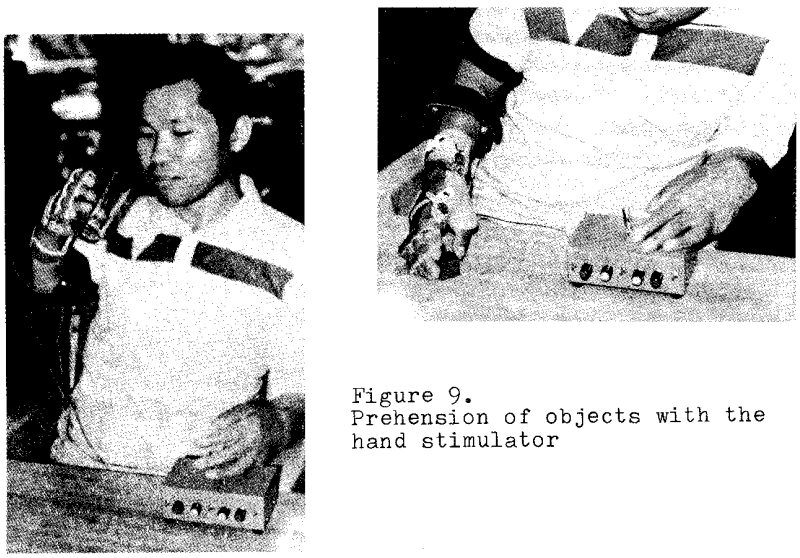

Figure 9.
Prehension of objects with the hand stimulator

Discussion

One of the advantages of FES is that it does not need external orthosis. However, in order to apply FES to upper-limb of quadriplegic patient today, use of supplemental hand

orthosis that stabilizes wrist and thumb in functional position and hold four fingers together is very practical. With aid of the orthosis, hand stimulator using surface electrodes has become useful for a C5 quadriplegic patient.

Even if control of FES for upper-limb should be proportional control, on/off control with gradually increasing stimulation strength was found extremely practical at this stage of developement. The greatest problem of hand stimulator using surface electrodes was unsatisfactory reliability of movement elicited by it. Next problem was insufficient force, particularly in flexion. We are now trying to increase prehension force using a splint with assistance of spring force.

CONCLUSION

1. Researchers of FES in Japan are increasing remarkably in recent years.
2. Hemiplegic patients who were in slight spasticity level and above stage IV of lower-limb functional level were good candidates for the peroneal stimulator.
3. The peroneal stimulator was very suitable for Japanese life style.
4. A C5 level quadriplegic patient with aid of a splint was able to restore minimum daily activities by the simplest hand stimulator using surface electrodes.

ACKNOWLEDGEMENT

Authors wish to express our thanks for carrying out clinical tests to Dr. Tamaki and Mr. Tamura, both of Toyama Medical and Pharmaceutical University; Mr. Ayuzawa, National Cardiovascular Center; Mr. Suzuki, National Kobe Hospital; and all the therapists at the Osaka Rosai Hospital. Furthermore, authors are indebted to Prof. Vodovnik, Ljubljana and Dr. Kakurai, Tokyo Metropolitan Prosthetic and Orthotic Research Institute for their suggestions and their kindness in offering us many literatures on this subject.

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