A Clinical Trial of a Prototype of Wireless Surface FES Rehabilitation System in Foot Drop Correction

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*Abstract***— The purpose of this study is to develop a wireless FES rehabilitation system to assist effective improvement of the lower limbs. In this report, a prototype system combined with foot drop correction and gait evaluation using wireless surface electrical stimulator and the wireless inertial sensors was developed and tested with a right hemiplegic subject. For gait evaluation, lower limb joint angles and segment angles were estimated by the Kalman filter from the data measured with wireless inertial sensors. Electrical stimulation was applied to the common peroneal nerve or the tibialis anterior muscle by detecting stimulus timing automatically from the data of wireless inertial sensor attached on the shank of the hemiplegic side. The maximum joint angle of ankle dorsiflexion of the paralyzed side at the swing phase was increased approximately to the value of the healthy side by applying the electrical stimulation. The developed system was performed well in foot drop correction and the measured data of the inertial sensors showed the characteristics and difference of paralyzed side with and without electrical stimulation using the segment angles and joint angles.**

I. INTRODUCTION

UNCTIONAL Electrical Stimulation (FES) has been utilized as an orthotic and therapeutic aid in the rehabilitation of the upper and lower limb motor functions. The therapeutic effects during rehabilitation with FES have been shown in improvement of muscle strength [1-3] and muscle recruitment [3-4]. The repetitive movement therapy mediated by the electrical stimulation also has the potential to facilitate motor relearning [5]. F

In training with FES for rehabilitation, goal-oriented repetitive movement training of the paralyzed limbs has been applied. Repetitive movements of limbs have to be controlled appropriately by stimulating the relevant muscles. Closed-loop FES control is required to suppress variations of initial position and muscle response, and muscle fatigue in the exercise and to derive benefit from the rehabilitation.

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On the other hand, FES may have important effects on the entire gait pattern beyond what can be attributed to improve the movement of the target limb alone [6]. For example, it is preferable to use motion measurement system for objective and quantitative evaluation of both the paralyzed and healthy limbs in rehabilitation training. Since inertial sensors such as a gyroscope and an accelerometer are small, low cost and easy for settings, they are suitable for clinical application. Many studies using inertial sensors have been performed independently in detecting gait phase, measurement of joint angles or segment tilt angle and detecting stimulus timing [7-9]. Therefore, an unified FES rehabilitation system for control and evaluation is expected to be effective in motor rehabilitation.

The purpose of this study is to develop an FES rehabilitation system composed of a wireless surface FES system combined with inertial sensors for detecting stimulus timing and for gait evaluation in rehabilitation. In this report, a prototype system was developed for foot drop correction and tested with a right hemiplegic subject. Lower limb joint angles and segment angles were measured with wireless inertial sensors for gait evaluation during the test.

II. SYSTEM

A. Wireless Surface FES Rehabilitation System

The prototype of wireless surface FES rehabilitation System consists of seven wireless inertial sensors (WAA-006, Wireless Technologies), a wireless surface electrical stimulator and a PC (Fig. 1). The measured data from the wireless inertial sensors attached on the lower limbs are transmitted to the PC and recorded for gait evaluation. The

stimulus timing is determined by using the measured data from the inertial sensors on the PC and stimulation data are transmitted to the wireless surface electrical stimulator.

B. Stimulus timing

On the PC, the stimulus timing is determined automatically by the acceleration data (x-axis) measured with the inertial sensor attached on the shank of the hemiplegic side. The change in the acceleration data during gait is characterized as follows:

- (a) negative value before the heel-off
- (b) positive value during the swing phase
- (c) large negative value due to the heel-strike
- (d) small value at the foot flat

The points (a) and (c) are considered to be suitable as the triggers to start and stop the stimulation, respectively. The data of the first step is used to identify the walking, and the stimulation is applied from the second step.

C. Surface electrical stimulator

The stimulus data are transmitted to the stimulator through the 2.4GHz wireless transceiver modules from the PC. The wireless surface stimulator generates electrical stimulation pulses immediately after receiving the stimulus data. Time delay has about 50ms from the onset of sending the stimulus command on the PC to the output of electrical stimulus pulse. The wireless surface electrical stimulator made up in our laboratory operates in 2 AAA batteries.

D. Wireless inertial sensor

The wireless sensor includes a 3-axis accelerometer (H30CD, Hitachi Metals), a 2-axis gyroscope (ID-400, InvenSense) and a 1-axis gyroscope (XV-3500CB, EPSON TOYOCOM). Therefore the sensor can measure 3-axis components of acceleration and angular velocity. The acceleration and angular velocity of the wireless inertial sensor attached on the feet, shanks, thighs of both legs and the lumbar region of the subject, which were fixed with stretching bands, are measured with a sampling frequency of 100Hz, and are transmitted to the PC via Bluetooth network. These data are recorded in the PC.

E. Estimation of joint and tilt angles using Kalman filter

In our previous study, it was shown that a method of estimating lower limb joint angles from outputs of gyroscopes and accelerometers using Kalman filter could measure the angles stably during gait [10]. In this paper, the measurement method of lower limb joint angles was modified to estimate the tilt angle of each inertial sensor. Figure 2 shows the block diagram of the modified system. *θ* is the tilt angle measured with a gyroscope and θ_a is the tilt angle measured with an accelerometer. Kalman filter is the method which estimates the state (actual signal) from the observation signal on the system of the state-space model. In our system, Kalman filter estimates the error of the tilt angle measured with a gyroscope Δ*θ'* from difference between angle obtained

with a gyroscope and that by an accelerometer Δy . Then, estimated tilt angle *θ'* is calculated by subtracting Δ*θ'* from *θ*. In this paper, we applied stationary Kalman filter instead of normal Kalman filter in order to reduce amount of calculations and to prevent larger error for a while after starting measurement because of the difference of initial state. Joint angle were calculated by using estimated the tilt angles of the segments.

III. EXPERIMENTAL METHOD

The developed system was tested in control and measurement with a right hemiplegic subject (male, 52 years old). Subject's consent to participate in the test was obtained. After attaching sensors, tilt angles of the foot, the shank, the thigh and the trunk and joint angles of the hip, knee and ankle joints measured during the quiet standing before the first trial were set as 0deg (Fig. 3). The subject was asked to walk 15m at the normal speed with or without electrical stimulation. The electrical stimulation was applied to the common peroneal nerve (CPN) or the tibialis anterior (TA). In the first 4 trials, the subject walked without electrical stimulation. Then, the subject walked with electrical stimulation, in which the applying method of electrical stimulation was selected randomly. Six trials for each applying method of the electrical stimulation were performed. The walking without electrical stimulation was performed between walkings with electrical stimulation. Pulse setting was monophasic pulse, 50ms period, 0.3ms width. Pulse amplitude was fixed at the value that was determined to develop maximum ankle dorsiflexion.

IV. RESULTS

The experimental results of 2 trial without electrical stimulation and 2 trial with electrical stimulation to the CPN

Fig. 2. Block diagram of tilt angle measurement system.

Fig. 3. Definition of each joint angle and each segment angle. Number and sign in parentheses indicate the value of joint angle or segment angle.

were excepted from the analysis because of trouble in measurement. Therefore, the results of 14 trials without electrical stimulation, 4 trials with electrical stimulation to the CPN and 6 trials with electrical stimulation to the TA muscle were analyzed.

A. Walk without electrical stimulation

The number of steps in the trials without electrical stimulation was 26 ± 1 steps. Walking speed was 0.91 ± 0.06 m/s, which were calculated from walking distance and time.

Figure 4 shows an example of measured joint angles and the foot strike event (\square) in the trial without electrical stimulation (Trial 5). The foot strike was identified by the large negative–positive acceleration (x-axis) changes measured with the inertial sensor on the foot. We focused on the maximum knee flexion at the swing phase (MKF) and the maximum ankle dorsiflexion at the swing phase (MAD) as shown in Fig. 4. These joint angles of the paralyzed side were small compared with the healthy side. Two peaks were caused at knee flexion of the paralyzed side.

Figure 5 shows an example of measured ankle joint angle, foot angle and shank angle in the trial without electrical stimulation (Trial 5). Around the MAD, the foot angle of the paralyzed side was smaller than the healthy side, which was about 10 deg and -10 deg for the healthy and paralyzed side, respectively in Fig. 5. At the foot strike, the foot angle of paralyzed side was about 0 deg, whereas the foot angle of the healthy side was about 20 deg.

Fig. 4. Lower limb joint angles without electrical stimulation (Trial 5). The maximum knee flexion at the swing phase (MKF), the maximum ankle dorsiflexion at the swing phase (MAD), and foot strike (\square) are shown.

Fig. 5. Ankle joint angle and segment angles of the foot and the shank without electrical stimulation (Trial 5). The maximum ankle dorsiflexion at the swing phase (MAD) and foot strike (\square) are shown.

Fig. 6. Lower limb joint angles and segment angles of the paralyzed side with electrical stimulation to the CPN (Trial 25). Duration of electrical stimulation is shown below the angle trajectories. The maximum ankle dorsiflexion at the swing phase (MAD), the maximum ankle plantar flexion at the swing phase (MAP) and foot strike (\square) are shown.

B. Walk with electrical stimulation

The numbers of steps in the trials with electrical stimulation to the TA muscle and the CPN were 26 ± 0.4 steps and 25 ± 0.7 steps, respectively. Walking speeds were $0.92 \pm$ 0.01 m/s and 0.91 ± 0.06 m/s, respectively. There were no differences of the number of steps and walking speed between with and without electrical stimulation.

Figure 6 shows an example of measured joint angles, the foot angle and shank angle of the paralyzed side in the trial with electrical stimulation to the CPN (Trial 25). The value of the ankle joint angle at the MAD and the foot angle around the MAD were increased by applying the electrical stimulation. In Fig. 6, value of the ankle joint angle was about 0 deg (or more) at the MAD and the foot angle was 0 deg at the MAD. The foot angle just before the foot strike was also increased to about 20 deg as with the healthy side.

V. DISCUSSION

The developed system performed appropriately in the correction of the foot drop during the walking. The maximum dorsiflexion angle of the paralyzed side without electrical stimulation was -11 ± 5.0 deg. Stimulation of the TA muscle and the CPN increased the maximum dorsiflexion angle (TA: -3.7 ± 3.4 deg, CPN: 3.5 ± 4.4 deg) approximately to the value of the healthy side (-1.6 ± 5.0 deg). The timings to start and stop electrical stimulation determined by the acceleration data on the shank were slightly before the maximum ankle plantar flexion at the swing phase (MAP) and around the foot strike (\square) , respectively, as seen in Fig. 6. In the preliminary measurement while sitting in the chair, the response time from the onset of sending command on the PC to beginning of dorsiflexion was about 200ms and about 120ms for stimulation to the CPN and the TA muscle, respectively. The time between the timing of the stimulus start and the detection of the maximum ankle dorsiflexion at the swing phase was about 400ms, which was longer than the response time in both stimulus conditions. The stop timing of electrical stimulation was similar to the timing of the foot strike. Therefore, it is considered that the length of stimulation time was detected appropriately and enough for producing the dorsiflexion.

The segment angles and the joint angles measured with the wireless inertial sensors showed the difference between walkings of the paralyzed side with and without electrical stimulation. As shown in Fig. 5 and Fig. 6, the measurement system using the inertial sensors showed information of foot movements in more detail. The foot angle of the paralyzed side at the foot strike was about 0 deg without electrical stimulation, which represents the foot were about parallel to the ground. By stimulating to the CPN, the foot angle increased to about 20 deg as with the healthy side just before the foot strike, which shows that the foot made strike with the ground on the heel as the healthy side. The results of joint angles and segment angles suggested that the measurement system using the inertial sensors would provide useful information for rehabilitation with FES.

VI. CONCLUSION

In this report, a prototype of FES rehabilitation system using a wireless surface electrical stimulator and seven wireless inertial sensors was developed for foot drop correction and gait evaluation, and tested with a right hemiplegic subject. The developed system performed appropriately in the correction of the foot drop during the walking. The measured data with wireless inertial sensors showed the difference between walkings of the paralyzed side with and without electrical stimulation using the segment angles and joint angles. The developed wireless surface FES rehabilitation system is expected to provide the effective rehabilitation with FES. Further studies are necessary to measure in the different walking conditions.

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