DEVELOPMENT OF A WIRELESS CURRENT CONTROLLED STIMULATOR FOR INDIVIDUALS WITH SPINAL CORD INJURY

AIZAN BIN MASDAR

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Special dedicated to my beloved wife Farhanahani Mahmud, my parents and my friends for their support and encouragement.

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ABSTRACT

A spinal cord injury (SCI) has a severe impact on human life in general as well as on the physical status and condition. The use of electrical signals to restore the function of paralyzed muscles is called functional electrical stimulation (FES). FES is a promising way to restore mobility to SCI by applying low-level electrical current to the paralyzed muscles so as to enhance that person's ability to function and live independently. However, due to the limited number of commercially available FES assisted exerciser systems and their rather high cost, the conventional devices are unaffordable for most peoples. Thus, this project is concerned with the development of low-cost current controlled stimulator mainly for the paraplegic subjects. The developed device is based on a microcontroller, wireless based system using Zigbee module, voltage-to-current converter circuit and should produce accurate monopolar and bipolar current pulses, pulse trains, arbitrary current waveforms, and a trigger output for FES applications. A simple low cost current adjustable circuit for electrical stimulator was designed and developed whose output consists of current pulses with a wide range of rectangular waveforms (monophasic/biphasic), ranging from 10-120mA with a step of 2mA and a time resolution of 10μs. The circuit also capable of adjusting the current amplitude, frequency and pulse width of the output signals. The advantages of the device are the high level of output current amplitude controlled by low level of control voltage, the capability of fine time and amplitude tuning, the vast range of output waveforms, wireless based system using zigbee module and the use of low cost electronics components in its structure which make it economically efficient for being used in various FES research studies as well.

ABSTRAK

Kecederaan saraf tunjang (SCI) mempunyai kesan yang teruk kepada kehidupan manusia secara umum dari segi fizikal dan keadaan. Penggunaan isyarat elektrik untuk memulihkan fungsi otot lumpuh dipanggil ‘rangsangan elektrik berfungsi’ (FES). FES adalah cara yang berupaya untuk memulihkan pergerakan keatas individu SCI dengan menggunakan arus elektrik tahap rendah kepada otot lumpuh sehingga dapat meningkatkan kemampuan individu itu untuk berfungsi dan hidup berdikari. Walau bagaimanapun, oleh kerana alat senaman FES mempunyai jumlah yang terhad di pasaran komersial dan kos yang agak tinggi, alat konvensional adalah mahal bagi kebanyakan individu. Oleh itu, projek ini adalah berkenaan dengan pembangunan alat FES dengan kos rendah untuk individu SCI. Alat yang dibangunkan adalah berdasarkan kepada mikropengawal, sistem berasaskan tanpa wayar yang menggunakan modul ZigBee, litar penukar voltan ke arus dan berupaya menghasilkan signal arus elektrik monopolar dan bipolar, pawai signal arus elektrik dan output pencetus untuk aplikasi FES. Litar laras kos rendah yang mudah untuk FES telah direka dan dibangunkan yang terdiri daripada signal arus elektrik dengan pelbagai bentuk gelombang segi empat tepat (monofasa/dwifasa), yang terdiri daripada 10-120 mA dengan unit terendah 2 mA dan resolusi masa 10μs. Litar ini juga mampu diubahsuai dari segi amplitud, frekuensi dan lebar signal arus output. Kelebihan alat ini adalah kebolehan mengeluarkan output amplitud tinggi berdasarkan kawalan voltan yang rendah, keupayaan penalaan amplitud dengan resolusi masa yang rendah, pelbagai bentuk gelombang output, sistem berasaskan tanpa wayar dan penggunaan komponen elektronik kos rendah yang berkesan untuk turut digunakan dalam pelbagai kajian penyelidikan FES.

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CHAPTER 1

INTRODUCTION

The loss of voluntary function in limbs and other body parts, also known as paralysis, is caused by disease or injury to the neuromuscular system. A subset of such disorders results from injury or disease that affects the central nervous system. Typical examples which lead to these disorders are stroke, spinal cord injury and traumatic brain injury. A common outcome of these injuries, which are classified as "central" since they occurred in the central nervous system, is that the lower motoneurons, which innervate muscles, remain intact. Thus, if electrical stimulation is applied to these neurons they can generate muscle contractions, which are otherwise paralyzed due to injury or disease to the central nervous system [1]. Since the early 1960's electrical stimulation has been used to artificially generate body functions such as walking, grasping, and hearing [2]. Various commercially available electronic stimulators have been developed to restore these functions [3-13]. The majority of them have been developed having one application in mind and thus have limited flexibility, i.e., cannot be applied to restore other body functions [2]. In recent years, it has been suggested that the creation of a single programmable, portable and multipurpose electrical stimulator would allow practitioners to apply electrical stimulation to diverse patients in various applications. One of the long term objectives of our team was to develop a portable and fully programmable electrical stimulator that can be used in various functional electrical stimulation (FES) applications. FES is the use of electrical stimulation to generate or restore specific body functions. The focus of this work was to conduct the appropriate research in relevant FES systems and applications, and use these results to develop the proof-of-concept controller subsystem that will be an integral part of the proposed FES system.

1.1 Motivation

Malaysian Institute of Road Safety Research (MIROS) carried out a study on both fatal and non-fatal injuries incurred by Malaysian motorcyclists from January to December 1998. For non-fatal injuries, the incidence of spinal injuries involving fracture of vertebra was 13 out of 226 patients (5.75%). For fatal injuries, no figures were reported on the incidence of spinal injuries. Interestingly, the number of neck injuries was reported to be 11 out of the 186 cases (5.9%). Some statistics of interest (Malaysia Spinal Injury Association - MASIA) There are about 12 to 53 new spinal injuries per million population in the developed countries every year. In the United States, at any one time there are 721 to 906 people with spinal cord injury per million population. The incidence (new spinal cord injuries) is expected to be much higher in our country. For example, in the Neurosurgical service in Sarawak General Hospital, there is a case of spine injury every month for patients admitted with head injury. There are more men injured compared to women in a ratio of 3.4:1. Typically these patients are young and two thirds of these occur in individuals less than 30 years of age. Motor vehicle accidents account for more than half of the spinal injury cases around the world. This however will vary from country to country. 20% to 57% of people with spinal cord injury also have significant injuries elsewhere. Up to 10% of spinal injury patients can have associated head injuries and about a quarter to half of head injury patients have a spinal cord injury. FES therapy has the potential to assist individuals who are moderately to severely affected by stroke or SCI in restoring voluntary motor functions. This rehabilitation technique has shown great promise. A considerable number of studies [1, 16-28] indicate that the use of FES as a form of rehabilitation therapy provides the ability to restore voluntary body functions in individuals suffering from paralysis. For example, results obtained from [18] in improving voluntary hand and body functions. Such results were attained from weekly training programs spanning 2 to 3 months pending patients' pathology and availability to participate in the training.

1.2 Problem statement

FES is a promising way to restore mobility to SCI by sending electrical signals to restore the function of paralyzed muscles. In this technique, low-level electrical current is applied to an individual with disability so as to enhance that person's ability to function and live independently [6]. It is important to understand that FES is not a cure for SCI, but it is an assistive device [7]. For SCI, the damage is only to the central nervous system, the muscle and its nerve supply remain healthy.

By using FES, the paralyzed muscle is possible to contract due to the reaction of the artificial electrical stimuli. FES system mainly consists of electrodes and a stimulator unit. Current pulses will be generated from the stimulator unit through the electrodes and these cause the paralyzed muscles to make contraction. The main objective of FES in injuries to the central nervous system is the substitution of the absent bioelectric activity with an appropriately formed series of electric pulses, generated by a stimulator, or the elimination of the hyperactivity in paralysis and spastic paresis [8]. Basically, two electrodes are essential to close the current circuit of the stimulation system as shown in Figure 1-1.

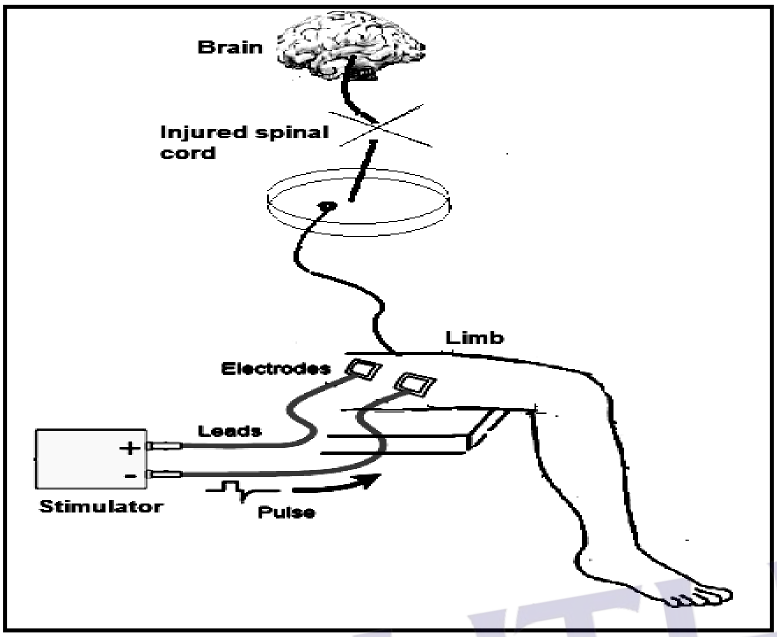

Figure 1-1 : A basic electrical stimulation system [5]

For many years, FES has been applied to restore or maintain muscle activities of paralyzed patients who suffer from spinal cord injuries and related neural impairments [9]. However, due to the limited number of commercially available FES assisted exerciser systems and their rather high cost, the conventional devices are unaffordable for most peoples. Moreover, it also inconvenient because of wired based system that creates a limitation in performing exercise.

1.3 Aim and objective

The development of low-cost and wireless based system current controlled stimulator for patients with spinal cord injuries are the aims of this research. The developed device is based on a voltage-to-current converter circuit, wireless based system and should produce accurate monopolar and bipolar current pulses, pulse trains, arbitrary current waveforms, and a trigger output for Functional Electrical Stimulation (FES) applications. To achieve these aims, the objectives of this research are formulated as follows:

i. To develop a low-cost FES circuit.
ii. To design a wireless based FES.
iii. To evaluate the proposed FES device performances through simulation study and validated through experimental work.

1.4 Scope

This device is mainly for SCI patients especially paraplegic subjects with using current controlled stimulator, zigbee wireless interface and surface electrodes method. A paraplegic is a patient who has lost some or all of the neurological function in their lower body.

1.5 Thesis contribution

This project is concerned with the development of low-cost current controlled stimulator mainly for the paraplegic subjects. The developed device will be based on a microcontroller, wireless based system using Zigbee module, voltage-to-current converter circuit and should produce proper monopolar and bipolar current pulses, pulse trains, arbitrary current waveforms, and a trigger output for FES applications. The performances of the device has be assessed through simulation study and validated through experimental work. This developed device as in the new technique of the stimulator development with low cost and one of the contributing factors in Rehabilitation Engineering for patients with SCI.

1.6 List of achievement

1.6.1 Journal paper

i. Aizan Masdar, B.S.K.K. Ibrahim and M. Mahadi Abdul Jamil, " Development of Low-Cost Current Controlled Stimulator for Paraplegics," International Journal of Integrated Engineering, Vol 4, No 3 (2012), p. 40-47.

ii. A. Masdar, B.S.K.K. Ibrahim, D.Hanafi, F.Mohd.Nor and M.M. Abdul Jamil, " Wireless-Based Current Controlled Stimulator With Knee Angle Measurement System for Rehabilitation," Journal of Engineering Technology Vol. 3: 32-39, 2013

1.6.2 Conference papers

i. Aizan Masdar, B.S.K.K. Ibrahim and M. Mahadi Abdul Jamil, " Development of Low-Cost Current Controlled Stimulator for Patients with Spinal Cord Injuries," Proceeding of National Conference of Electric and Electronic Engineering (NCEEE), 2012, pp. 124-129.

ii. Aizan Masdar, B.S.K.K. Ibrahim and M. Mahadi Abdul Jamil, " Development of Wireless-Based Low-Cost Current Controlled Stimulator for Patients with Spinal Cord Injuries," 2012 IEEE-EMBS Proceeding of International Conference on Biomedical Engineering & Sciences (IECBES), Dec 2012, Langkawi, Malaysia.

iii. Aizan Masdar, B.S.K.K. Ibrahim, M. Mahadi Abdul Jamil, Dirman Hanafi, M. K.I. Ahmad and K.A.A. Rahman, " Current Source with Low Voltage Controlled for Surface Electrical Stimulation," 2013 IEEE 9th International Colloquium on Signal Processing and its Applications (CSPA), Mac 2013, Kuala Lumpur, Malaysia.

iv. Aizan Masdar, B.S.K.K. Ibrahim, M. Mahadi Abdul Jamil and Dirman Hanafi, " Wireless Surface Electrical Stimulation With Knee Joint Angle Measurement System Using Gyroscope and FlexBend Sensors," 2nd International Conference and Exhibition on Biosensors & Bioelectronics, 17-19 June 2013, Hilton Chicago/Northbrook, USA.

v. Aizan Masdar, B.S.K.K. Ibrahim, M. Mahadi Abdul Jamil, Dirman Hanafi and K.A.A Rahman, " Knee Joint Angle Measurement System Using Gyroscope and Flex-Sensors for Rehabilitation," The 6th Biomedical Engineering International Conference (BMEiCON2013), 23-25 Oct 2013, Pavilion Queen's bay Krabi, Thailand.

1.6.3 Competition

i. Participated in the Research & Innovation Festival 2012 (R&I Fest 2012) at Universiti Tun Hussein Onn, Batu Pahat, Malaysia with the title " Development of Low-Cost Current Controlled Stimulator for Patients with Spinal Cord Injuries,"

1.6.4 Grant

i. Prototype Development Research Grant Scheme (PRGS) with amount of RM87,000 has been granted to complete this project.

1.6.5 Intellectual Property (IP)

i. A Wireless Controlled Electrical Stimulator (Application No.: PI2014003466) has been filed.

1.7 Thesis Overview

This thesis describes a controller subsystem for use in the novel FES system being developed and it is organized as follows.

Chapter 2 goes over the required background research conducted in the area of FES neuroprostheses, including stimulation characteristics, relevant applications and previously developed FES systems.

Chapter 3 presents the methodology and the newly proposed FES system, including information on the overall system concept.

Chapter 4 provides an overview of the hardware and software system requirements and the high-level system design decisions on which the rest of the project is based on; including decisions on hardware platform, development software and structure concentrate on the components, which make up the controller subsystem.

Chapter 5 presents the experimental setup and results which have been used to verify and validate the system's design and operation.

Chapter 6 presents the conclusion and future work of this project.

CHAPTER 2

A BRIEF REVIEW ON THE RELATED WORKS

This chapter provides the required background information pertaining to FES systems, starting with a physiological overview of electrical stimulation and brief history of neuroprostheses. Then, the research results associated to the present state of the art in the FES field including potential applications and operating ranges of existing FES devices are presented.

2.1 Physiological Overview

Information in nerve cells is coded and transmitted as series of electrical impulses called action potentials (AP), which represent brief changes in cell electric potential of about 80 mV. APs can be artificially generated by inducing electric charge into the nerve cell or nerve axon. The intensity of the signal transmitted is direct proportional to the frequency of APs that occur in the axon per unit of time. When APs are generated using electrical stimulation and are used to produce a body function, it is referred to as FES. During FES, for every AP that propagates towards the end of the axon that is innervating a muscle, one AP will propagate backwards towards the cell body of the motoneuron [2]. FES is typically concerned with innervating a muscle as they generate muscle contractions in order to produce the desirable body function. In the case when the APs are generated by the central nervous system (instead of FES), the cell body receives AP driven inputs from dendrites, it summates the excitatory and inhibitory APs, processes them and decides whether or not to generate an output AP. Following stroke or SCI the motoneurons do not receive appropriate input from the central nervous system therefore inhibiting muscle function. FES replaces this functionality by artificially generating required AP's to elicit a desired musclelimb function. A neuroprosthesis is an FES device that provides short bursts of electrical impulses to the central or peripheral nervous system in order to generate sensory and motor function. Some example neuroprostheses, which have been developed in the past 40 years, include cochlear implants, bladder management stimulator systems, walking and grasping neuroprostheses [2]. Common components found in each neuroprostheses include a power source, a controller, a stimulus generator, user interface and electrodes. Nerves can be stimulated using surface, percutaneous or implanted electrodes. The stimulation waveforms are realized through current or voltage pulses which can be monophasic or biphasic. Monophasic pulses which deliver a single mono-polar pulse at a time are not usually used as they lead to an unbalanced charge delivery to the tissue, which can cause tissue damage [30]. Most modern FES systems implement biphasic current or voltage pulses, where the first pulse evokes an action potential and the following pulse removes the delivered charge, thereby preventing tissue damage from accumulated charge in the surrounding tissue.

2.2 Brief history

The first “electric stimulators” may be dated back to 46 A.D. by Scribonius Largus, a physicist from Neron and physician to the Roman Emperor Claudius who applied electrical currents from the torpedo fish to treat various ailments such as headaches and painful gout [31]. The breakthrough in the medical use of electricity came from the invention of the electrostatic generator (~1663) and the discovery of the Leyden jar (1745) – the origin of the capacitor [31-32]. In 1766 Johann Gottlieb Scäffer published a book which provided a detailed description of the use of electrical discharges for treatments associated with paralysis and pain [32]. According to Scäffer, the greatest therapeutic effect was obtained with “shaking electricity” – when sparks were used to transmit the electricity to the patient, inducing strong muscular switches. In the early 1960s, Liberson and colleagues developed a simple neuroprostheses intended to correct drop foot. Drop foot is characterized by a lack of dorsiflexion during the swing phase of gait, resulting in short shuffling strides [33]. Liberson’s device is known as the first neuroprostheses which received a patent and was the initial push towards FES systems and devices. Liberson’s neuroprosthesis is comprised of a power supply worn on a belt, two surface electrodes to stimulate the common peroneal nerve, and a heel switch. The stimulation was activated whenever the heel rose off the ground and deactivated when the heel contacts the ground.

2.3 Stimulation Characteristics

FES systems use electrical signals to activate nerve fibers and muscles in order to perform the desired function, these signals can be characterized in terms of shape, frequency, pulse-width (PW) and amplitude. Controlling stimulation parameters as a function of time, temporal activation of individual channels, and overall stimulation patterns are key aspects in the development of custom neuroprostheses.

2.3.1 Stimulation Waveforms

Throughout the years various stimulation waveforms have been used to provide neural excitation. These stimulation waveforms can be grouped into direct current (DC) flow (A), alternating current (AC) flow (B) or pulse shaped current flow (C). DC waveforms have been used clinically to increase circulation, to treat neuralgia, for electrolysis and as a tool for iontophoresis (transfer of ions through the skin) [30]. This type of stimulation waveform does not provide the means to activate muscle contractions; rather it produces muscle twitches associated with the start and end of the DC waveform. AC waveforms are defined as a constant current flow moving in one direction and then in the reverse direction. These waveforms can be of any shape including sinusoidal, square, triangular, and trapezoidal. Common characteristic of such waveforms are the lack of electrical silence between phases. Similar to DC waveforms, AC waveforms are not usually used for therapeutic stimulation, unless they are packaged into on-off envelopes (with electrical silence between each envelope) or further modulation. Low frequency sinusoidal stimulation is known to be effective in activating denervated muscles [34]. Pulse

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