A One-time Implantable Wireless Power Bidirectional Transmission Spinal Cord Stimulation System

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***Abstract*—This study presents a prototype of a one-time implantable spinal cord stimulation system (SCS) using wireless power and bidirectional data transmission by an inductive link. The data can be transmitted by an inductive link, which is based on a duplex ASK-LSK technique. A fabrication chip is integrated in the bio-implant to generate stimulation waveform control signals. The chip area is 1800 $\times$ 1250 μm^2. The proposed SCS system attain better flexibility of operation modes than that of a commercial product, i.e., Medtronic Itrel 3 7425.**

***Index Terms*—spinal cord stimulation, SCS, wireless power transmission, duplex ASK-LSK, low power**

I. Introduction

Electrical stimulation has been a well known technique for a long time to assist patients in convalescence. In 1965, a "gate control" stimulation theory was first presented by Melzack *et al.* [1]. Furthermore, a spinal cord stimulation (SCS) method based on the gate control theory to treat the chronically neuropathic pain [2]. The first report about the analgesic effect in clinical experiments was presented in 1971 [3]. However, the rationale for the gate control theory utilized a special electrical pulses to stimulate the somatosensory nerve fibers via a stimulating electrode array such that the pain can be significantly mitigated. Thus, the SCS technique was justified to effectively reduce the dependency of morphine such that the medicinal addiction can be prevented.

In general, the stimulating pulses are generated by a pulse generator in the SCS system, which provide three kinds of stimulation modes, mono-, bi-, and tripolar, to cope with different demands of clinicals. Many kinds of the SCS systems are designed for the fully implantable devices. The pulse generater will be replaced if the battery is dead. To reduce the discomfortness caused by the replacement surgery, long operating time of the battery is the key research point of the pulse generator. Therefore, low power circuit design is required for this regard. Lately, the cost of the commercial SCS products is very expensive for the patients (around 20,000 USD). Fortunately, thanks to the fast evolution of semiconductor and wireless communication technologies, the demands of the SCS system, e.g., low cost, low power, and small size, are possibly realized easily.

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This paper proposes a prototype of rechargeable one-time implantable SCS system. The Li-ion battery is adopted to store excess power in the Internal Module. Moreover, an SOC (system on chip) is designed and integrated in this system to be a stimulating pulse controller.

II. Rechargeable One-time Implantable SCS System

Fig. 1 shows the proposed SCS system. The skin of human is assumed to be located between the External Module and the Internal Module. The wireless communication technique adopts an ASK (amplitude-shift keying) (inward) and a LSK (outward) methods. The power and command packets can be transmitted to the Internal module by a inductive link of the pair of the coils. On the other hand, the SCS status can also be transmitted to the external module by the inductive link simultaneously. The detailed descriptions of each block are described as in the following sections.

A. External Module

The External Module is composed of an FPGA (field programmable gate array), a Class E Transmitter, an External Coil, and a LSK (load-shift keying) Demodulator. The FPGA is used to generate the serial digital signal output according to the packet of the configuration settings for the user. The digital signal is sent to the Class E Transmitter to be modulated which is then transmitted from the External Coil to the Internal Coil by the inductive link. Fig. 2 shows the schematic of the Class E Transmitter and the LSK Demodulator. The description of Fig. 2 is given as follows.

Class E Transmitter: The digital packet signal from the FPGA is presented to the input, Data in, of the Class E Transmitter. The current variation at node A depends on the state of M1, which leads the emitter current of B0 to be changed intensely. Notably, the current through the inductor, L0, makes the choke inhibits impulses at the drain of M0. Besides, the frequency of carrier wave is determined by the switching rate of the gate drive signal, carrier wave, of M0. By mixing the choke's inhibiting impulses and the carrier wave, the modulation signal is generated via C1, which is sent to the Internal Module by the inductive link. Notably, the data transmission approach is based on an ASK (amplitude-shift keying) modulation technique [4].

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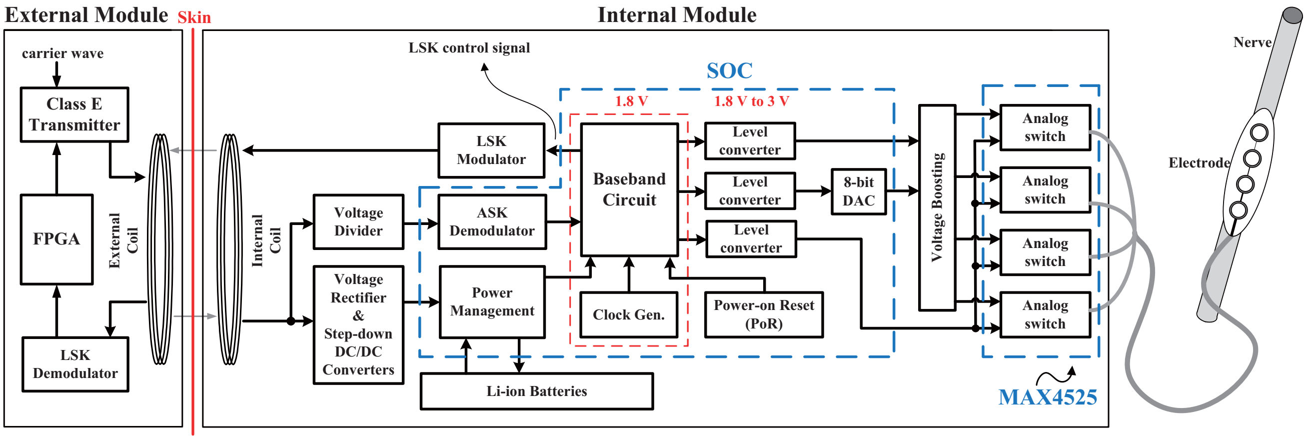

Fig. 1. Block diagram of the proposed SCS system

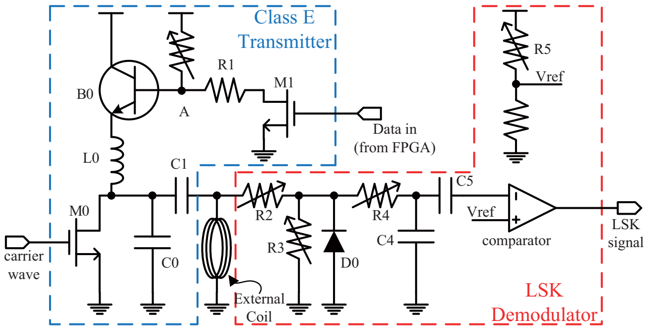

Fig. 2. Schematic of the Class E Transmitter and the LSK Demodulator

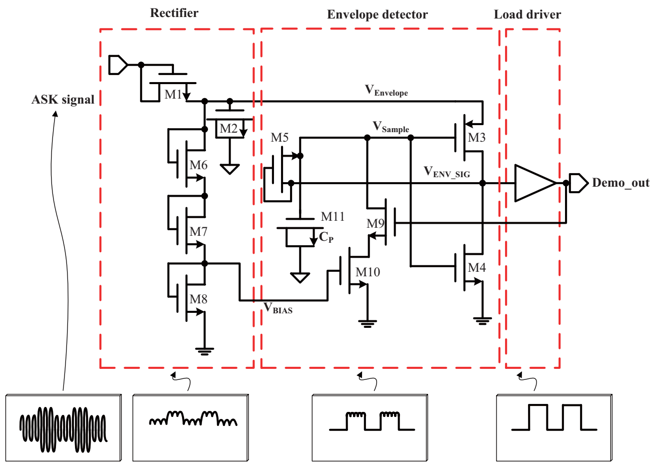

Fig. 3. Schematic of the ASK Demodulator

LSK Demodulator: The LSK modulation method utilizes an impedance reflection technique, which is usually adopted in RFID (radio-frequency identification) or biomedical systems [5]. When the load impedance variation of the internal LSK Modulator is reflected to the External Coil by the inductive link, the resonant point leading the amplitude of the modulation signal is changed. The aim of the divided resistor series, R2 and R3, is used to reduce the modulation signal to an appropriate voltage, which the diode, D0, is used to be a half-wave rectification. A low pass filter is composed of R4 and C4, which is adopted to smooth the half-wave modulation signal, which will be passed through C5 to the negative input of comparator. By comparing with Vref, the output, LSK signal, can be recovered to the same as internal LSK control signal from the Baseband Circuit.

B. Internal Module

The Internal Module is composed of the SOC (system on chip), the Li-ion batteries, analog switch ICs (MAX4525), and other off-chip discreteness. According to the external control signal, Internal Module (or called pulse generator) generates corresponding stimulating waveforms to the nerves. The detailed description of each block is described as follows.

ASK Demodulator: The proposed ASK Demodulator is employed to demodulate the modulation signal received by the Internal Coil into a digital signal, which is shown in Fig. 3. Because the amplitude of the modulation signal form the Internal Coil is large, the modulation signal must be reduced into an appropriate potential by Voltage Divider to the ASK Demodulator. The the modulation signal is rectified to a half-wave by the Rectifier. The Envelope detector is adopted to enhance the headroom of the rectified half-wave. The Load driver is basically a CMOS buffer, which is used to improve the fan-out capability. By using the ASK Demodulator, Demo_out can be restored the same as the external digitally serial data.

Power Management: The Power Management is used to supply the power of the entire SCS system and store the excessive power from the inductive power into the Li-ion batteries.

Baseband Circuit: The Baseband Circuit is a digital controller, which can generate all of the stimulating control signals to control the off-chip stimulating circuits according to the input packet from the ASK Demodulator. To reduce the power dissipation, the Baseband Circuit adopts 1.8 V supply voltage.

However, it utilizes the Level converters to convert the swing of stimulating control signals into 3 V for the output.

LSK Modulator: Referring to the prior work [6], when the Baseband Circuit completes a period of packet verification process, the LSK control signal is pulled high to enable the LSK Modulator such that the internal modulation wave of the Internal Coil is changed. Thus, the amplitude of the External Coil is changed as well. The LSK Demodulator can demodulate the changed external modulation wave into a digital waveform according to the amplitude of the External Coil, which will notify the FPGA to determine the status of Internal Module.

Clock Generator: The 1.0 MHz Clock Generator is based on a ring oscillator structure, which can be found in many prior works.

Power-on Reset (PoR): To avoid any possible unwanted situation, the PoR is required to generate a pulse to reset the Basedband Circuit into an initial condition when power is on.

8-bit DAC (Digital-to-analog converter): The 8-bit DAC is used to generate a stimulating voltage reference to the Voltage Boosting to produce an appropriate amplitude for the stimulating waveforms.

Voltage Boosting: The maximum output voltage of the stimulating voltage reference from the 8-bit DAC is only 3 V. The specification of the stimulating waveform amplitude, however, is limited in 0 to 10.5 V. Therefore, the Voltage Boosting circuit depending on the 8-bit DAC output to generate a voltage amplitude for the stimulating signal.

Analog switch: This proposed SCS system uses MAX4525 Analog switches to generate the positive phase stimulating and negative stimulating by two input control signals from the Baseband Circuit through a Level converter. The generant stimulating waveform via the lead to the Electrode is applied on the nerve.

III. Simulation and Implementation

TSMC (Taiwan Semiconductor Manufacturing Company) standard 0.18 μm CMOS technology is adopted to carry out the proposed Baseband Circuit. Fig. 4 shows the die photo of the proposed Baseband Circuit, where the area is 1800 $\times$ 1250 μm^2. Fig. 6 exhibits the modulation signals of the External Coil and Internal Coil. The modulation signal of the Internal Coil can be demodulated to a serial of digital signals by the ASK Demodulator. The LSK control signal is given to the LSK Modulator to change the load impedance, which is then reflected to the External Coil. Thus, the amplitude of the External Coil's modulation signal is changed as well. Furthermore, the rectified signal of the External Coil and the LSK demodulation signal are shown in Fig. 7. The LSK demodulation signal is the same the LSK control signal. Therefore, the full-duplex transmission is realized. Fig. 8-9 show the stimulation waves, which are, respectively, measured in different conditions. The specification compared with Medtronic Itrel 3 7425 is tabulated in Table I.

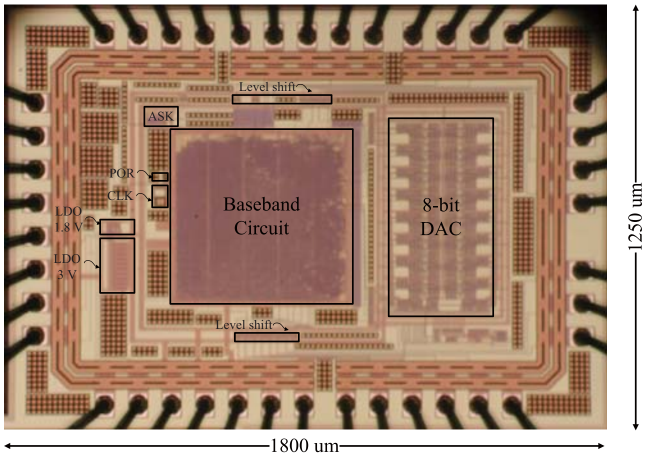

Fig. 4. Die photo of the proposed B SCS system

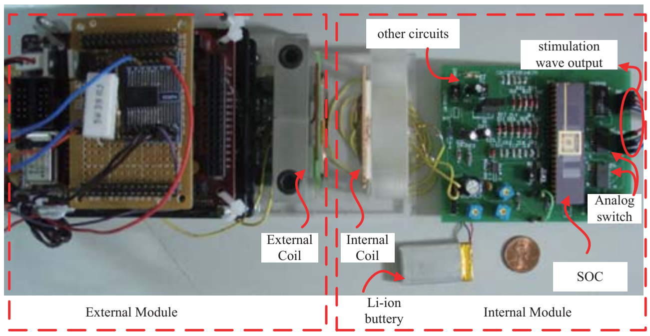

Fig. 5. Photograph of the proposed SCS system

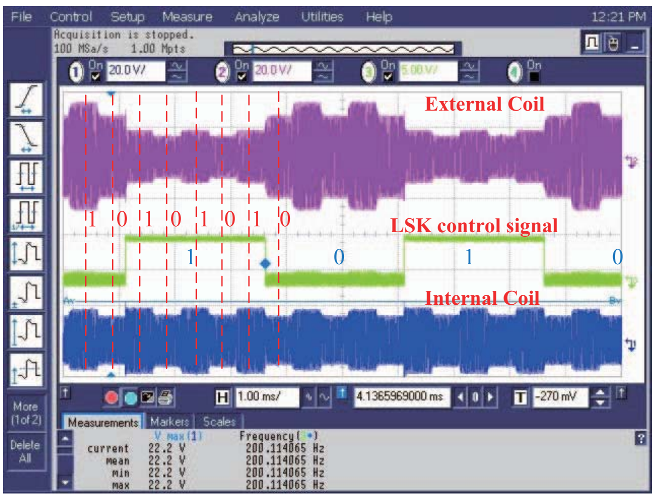

Fig. 6. Measurement of the modulation signal

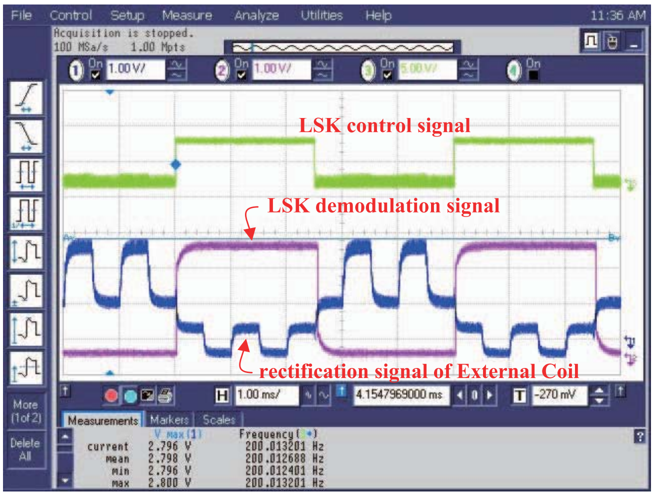

Fig. 7. Measurement of the LSK demodulation

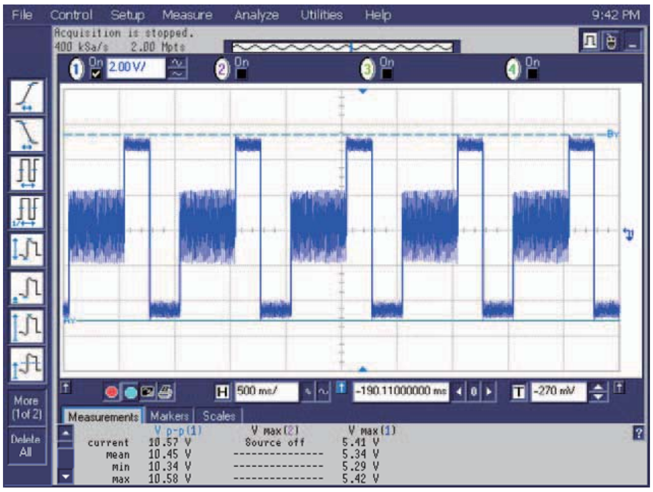

Fig. 8. Measurement of the stimulation wave (5.4 V at 1K Hz)

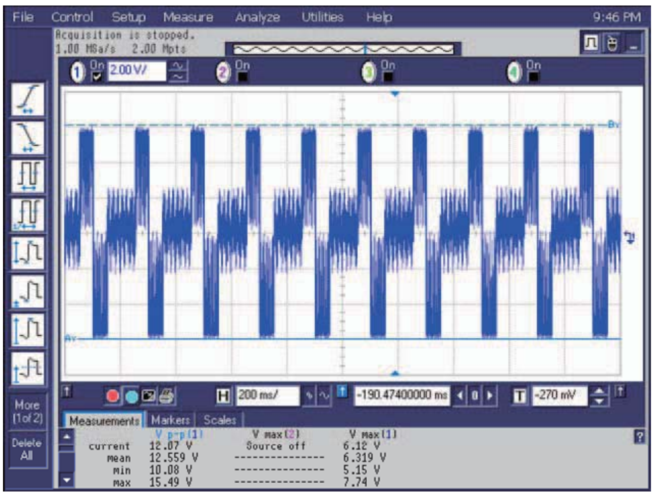

Fig. 9. Measurement of the stimulation wave (6 V at 10K Hz)

TABLE I
Comparison of the commercial SCS systems

Device	7425	Ours
#Electrode supported	4	4
Data rate	N/A	100 bps
RF Band	N/A	2.0/13.56 MHz
Stimulation frequency	2.1 Hz ~ 130 Hz	2 Hz ~ 150 Hz
Duration of stimulation	15m ~ 75m	1m ~ 75m
Storage temperature	-18℃ ~ +52℃	-18℃ ~ +52℃
Amplitude	Normal 0.0 ~ 10.5 V	0.0 ~ 10.5 V
	Fine 0.0 ~ 6.35 V	
Pulse width	60us ~ 450us	60us ~ 450us
Power dissipation	N/A	≦200 mW
Sleep/Charge/Stimulate mode	No charge mode	Yes
Battery supported	Yes	Yes (optional)

IV. Conclusion

This paper proposes a prototype of an one-time implantable wireless power and bidirectional transmission spinal cord stimulation (SCS) system. By using the duplex ASK-LSK technique, the data can be transmitted by an inductive link. Moreover, the power is also transmitted via the inductive link to supply the Internal Module circuit. To extend the life time, a Li-ion battery is adopted to store the excess power in the Internal Module. Compared with the specification of the commercial product, Medtronic Itrel 3 7425, the proposed SCS system has better flexibility and long operating time.

Acknowledgement

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