Published in final edited form as:

IEEE Trans Circuits Syst II Express Briefs. 2019 May ; 66(5): 783–787. doi:10.1109/TCSII.2019.2908072.

Gastric Seed: Towards Distributed Ultrasonically Interrogated Millimeter-Sized Implants for Large-Scale Gastric Electrical-Wave Recording

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Abstract

This paper presents the concept of Gastric Seed, which is an ultrasonically interrogated millimeter-sized implant for gastric electrical-wave (also known as slow waves, SWs) recording. A network of Gastric Seeds can be endoscopically implanted within the stomach submucosal space for large-scale SW recording. This paper also summarizes our recent effort towards Gastric Seed development including ultrasonic self-regulated power management and addressable ultrasonic pulse-based data transfer. The proposed power management in the form of a voltage doubler only requires a single off-chip capacitor for simultaneous rectification, regulation and over-voltage protection (OVP) by utilizing ultrasonic transducer's internal capacitance and reverse current. For data transfer, sharp ultrasonic pulses are transmitted to reduce the implant's power consumption. A proof-of-concept addressable chip was fabricated in a 0.35- μm standard CMOS process. Utilizing two pairs of millimeter-sized stacked power/data ultrasonic transducers spaced by 3.75 cm in a water tank, the chip achieved measured regulated voltage of 3 V and data rate of 75 kbps with the data transmitter energy consumption of 440 pJ/bit.

Index Terms—

ultrasound; gastric neurophysiology; power management; pulse-based data transfer; ultrasonic wireless link

I. INTRODUCTION

Gastric contractions are initiated and coordinated by an underlying bioelectrical activity, termed slow waves (SWs) [1]. Aberrant SW patterns (dysrhythmias) have been associated with gastric dysmotility in several significant gastric motility disorders, such as gastroparesis (GP) [2] and functional dyspepsia (FD) [3]. GP is a chronic debilitating disease with symptoms including continuous nausea and vomiting, affecting more than 1.5 million people in the US. Up to 30–50% and 16–30% of patients with type 1 and 2 diabetes suffer from GP or related symptoms, respectively. This number is increasing due to the diabetes epidemic,

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with hospitalizations rising 150% in the last decade with major associated costs [2]. FD is a chronic disorder characterized by upper abdominal pain, bloating and early satiety. FD approximately affects up to 15–30% of the US population with vast associated economic burden [3].

High-resolution mapping of gastric electrical activity by recording SWs has shown potential to elucidate the mechanisms underlying gastric dysrhythmias. Unfortunately, noninvasive techniques have limited accuracy and are highly prone to motion artifacts [4]. Although current implantable approaches offer high resolution, they are highly invasive in that electrode wires traversing the abdominal wall, or a natural orifice pose risks of discomfort, dislodgement or infection.

To eliminate the issues involved in wired systems, wireless systems have been recently developed for SW recording [5],[6]. The system in [5] has been designed with commercial off-the-shelf (COTS) components, thus suffering from limited number of recording channels (only 7), being bulky, and high-power consumption. Although the inductively interrogated (inductive power and data transfer) system in [6], comprising of an implantable chip with 64 recording channels attached to an electrode array, obviates some of above issues, it still suffers from motion artifacts (noisy signal acquisition) and damage to the enteric nervous system due to its bulkiness (centimetersized), and also only acquires SWs from a limited portion of the stomach.

We propose a new paradigm for large-scale gastric interfacing to eliminate the aforementioned shortcomings by developing a network of distributed, minimally invasive (millimetersized), ultrasonically interrogated implants, called Gastric Seeds (Fig. 1), that are envisioned to be 1) small (10 mm^3), light, and wireless to minimize motion artifacts, tissue damage, and risk of infection and expulsion, and 2) modular to acquire SWs from the whole stomach through independent interrogation of each individual Gastric Seed with a specific address (ID). Similar to [5], [6], Gastric Seeds can also be endoscopically implanted within the stomach submucosal space. Ultrasound for wireless power and data transmission to millimeter-sized implants has been demonstrated in several works [7]. As shown in [8], ultrasound can provide better power efficiency for powering deep millimeter-sized implants. However, current ultrasonic systems don't have SW recording capability, are designed for a single implant (not a distributed addressable network) and employ either power-hungry carrier-based data transfer or weak backscattering via load modulation, which is only good for short distances.

In this paper, we present the Gastric Seed concept and our recent effort towards the development of Gastric Seed. A proof-of-concept chip prototype of Gastric Seed will be presented with emphasis on its novel features of ultrasonic self-regulated integrated power management, low-power pulse-based data transfer, and addressability. The Gastric Seed concept will be presented in Section II. In Section III, the chip design will be discussed in detail. The chip measurement results will be presented in Section IV, followed by conclusion remarks in Section V.

II. GASTRIC SEED CONCEPT

Fig. 1 shows the conceptual diagram of the proposed technology. It includes a network of implantable Gastric Seeds, a Wearable Unit (WU), and a Stationary Unit (SU). The WU, envisioned to be developed on a flexible printed-circuit board (PCB) in the form of a belly band worn by the subject (to cover the whole stomach from all directions), will consist of an array of stacked ultrasonic (US) power and data transducers (power transmitter, Tx, and data receiver, Rx, in Fig. 1). The power Tx transducers will ultrasonically power up distributed Gastric Seeds, and also modulate Gastric Seed IDs on the power carrier for continuously interrogating Gastric Seeds one at a time. The data Rx recovers data pulses (SW signals) sent by Gastric Seeds. Each Gastric Seed in Fig. 1 with the envisioned size of $\sim 10 \text{ mm}^3$ will integrate a CMOS chip for differential SW recording and two stacked US transducers (power Rx and data Tx) on a substrate, on the back of which two recording pads are printed. The power Rx transducer will wirelessly receive power along with amplitude-modulated interrogation data (ID) from WU. The data Tx transducer will wirelessly transmit the recorded SW signals to WU using narrow pulses. Similar to [7], power and data transmissions can be time-multiplexed to avoid interference on the data link. The SU receives SWs for real-time display and mapping of the stomach activity.

As shown in Fig. 1, the proposed Gastric Seed requires several state-of-the-art core technologies. In this paper, we will only present our latest progress on self-regulated power management and pulse-based data communication for a single addressable Gastric Seed. We are currently working on robust ultrasonic interrogation of a network of Gastric Seeds, which will be presented in our future publications.

III. GASTRIC SEED CHIP ARCHITECTURE

Fig. 2 shows the simplified diagram of the proposed Gastric Seed chip, including an analog frontend (AFE), a pulse-based data Tx, and self-regulated power management. The AFE, which is not discussed in this paper and will be disclosed in our future publications, will include a tuned low-noise amplifier (LNA) and a 10-bit successive approximation register analog-to-digital converter (SAR-ADC). The chip externally requires one capacitor (C_L) and a pair of stacked millimetersized power and data ultrasonic transducers.

A. Self-Regulated Power Management

An integrated power management typically requires two large capacitors for rectification and regulation [7], and often an additional large capacitor for over-voltage-protection (OVP). To implement a voltage doubler, even another large capacitor is also required. However, in a millimeter-sized implant minimum number of large capacitors should be used. As shown in Fig. 2, the proposed power management is in the form of a voltage doubler and can perform rectification, regulation and over-voltage-protection (OVP) in one step with only one off-chip capacitor (C_L). A switch controller block generates a switching signal (S) to control the pass transistor (M_2) acting as an active switch. Considering the inherent internal capacitance of the power ultrasonic transducer (power Rx), the voltage doubler is implemented by connecting the diode-connected transistor (M_1) in parallel with the transducer, technically eliminating the need for 3 large capacitors.

Fig. 3 shows the switch controller schematic diagram along with its key operational waveforms for self-regulation of V_L at 3 V utilizing reverse current from C_L to the ultrasonic transducer only when V_L surpasses 3 V. Inside the switch controller, an amplifier (Amp) controls the bias current (I_{bias}) of a comparator (Comp), comparing V_L with the received voltage (V_P) as in an active rectifier, by amplifying the difference between $0.38 \times V_L$ and $V_{BG}R = 1.15$ V. If $V_L < 3$ V, the amplifier outputs low and I_{bias} is maximized. Therefore, the comparator operates at its highest speed to maximize the forward current flowing from the ultrasonic transducer to C_L when $V_P > V_L$ and block the reverse current when $V_P < V_L$. This ensures highest power conversion efficiency (PCE) in charging C_L . When V_L surpasses 3 V, the amplifier reduces I_{bias} that slows down the comparator during turn-off (increasing S pulse width) and allows reverse current to flow from C_L to the transducer (also loading the transducer), reducing V_L as shown in the Fig. 3 inset. This iterative process self-regulates V_L at 3 V.

B. Addressable Pulse-Based Data Communication

To demonstrate the concept of addressable Gastric Seeds, the chip in Fig. 2 was designed to externally be assigned two IDs, “0” and “1”. To enable IDs “0” and “1”, the power carrier is modulated with a 20 μ s activation notch followed by nothing or a second 20 μ s notch after 5 μ s, respectively. The number of IDs can be easily scaled up by using similar amplitude modulation of the power carrier with more bits. Upon activation, the Gastric Seed transmits 15 bits in the form of sharp pulses with 140 ns width for high bits and nothing for low bits (on-off keying modulation). These 15 bits include one bit for supply check (high: $V_L > 2.8$ V), 3 start bits (“101”), ten digitized recorded data bits and one end bit (high).

Fig. 4 shows the schematic diagram and key operational waveforms of the address (ID) check block, in which V_P envelope is first recovered. Then, the rising edge of the activation notch (X), triggering $FF1$ flip-flip, is delayed by 15 μ s (Y) to trigger $FF2$, detecting the address ($addr$) command of either “1” or “0”. When $addr$ is high, Gastric Seed with ID = “0” is enabled by setting S_0_EN low and consequently Tx_EN_0 high as shown in the Fig. 4 waveforms. Similarly, Gastric Seed with ID = “1” is enabled when $addr$ is low (Tx_EN_1 : high). The $START$ and RST signals in Fig. 4 are generated internally at the beginning and end of each 15-bit data frame.

IV. MEASUREMENT RESULTS

Fig. 5 shows the die micrograph of the proof-of-concept Gastric Seed chip, fabricated in a 0.35- μ m 2P4M CMOS process, occupying 0.6 mm² and 0.4 mm² with and without pads, respectively. The chip operates at the power carrier frequency (f_p) of 1 MHz to regulate V_L at 3 V ($C_L = 10$ μ F).

Fig. 6 shows the measurement setup. The ultrasonic transducers (PZT-5A, APC International, Mackeyville, PA) with desired resonance frequency of ~ 1 MHz for power/data transfer were held perfectly aligned with a separation of 3.75 cm inside a water tank, made of Plexiglas. The proof-of-concept stacked transducers for data-Tx (diameter: 1.1 mm, thickness: 0.2 mm) / power-Rx (diameter: 1.1 mm, thickness: 0.9 mm, parasitic capacitance: 37.5 pF) were assembled on a PCB and located at the tank’s bottom surface with a 3D-

printed holder. The power Tx (Data Rx) transducer (diameter: 15.9 mm, thickness: 2 mm, resistance at resonance: $\sim 400 \Omega$) was glued to an adjustable 3D-printed plastic stand that could move in all three axes (Fig. 6). Transducers were encapsulated by biocompatible Sylgard-184 with the same acoustic properties as water.

Fig. 7a shows the measured PCE and voltage conversion efficiency ($VCE = V_L / 0.5 V_{P,peak-peak}$) of the power management at different DC load resistances ($R_{L,DC}$) with no reverse current. The highest PCE of 83.8% at $R_{L,DC}$ of 30 k Ω ($\sim 200 \mu W$ of power consumption) was achieved. For regulation, the PCE is intentionally reduced with reverse current when V_L surpasses 3 V. Thanks to the proposed voltage-doubler method, a high VCE of 1.7 V/V was achieved for most $R_{L,DC}$ values. Fig. 7b shows the power transfer efficiency (PTE) of the ultrasonic link at different AC load resistances ($R_{L,AC}$). The highest PTE of 0.52% was achieved at $R_{L,AC} = 8 k \Omega$. Considering average PCE of 80% and VCE of 1.7 V/V, $R_{L,DC}$ of the power management is seen almost 7–8 times smaller by the ultrasonic link as $R_{L,AC}$. Therefore, at $R_{L,DC}$ of 30 k ($R_{L,AC} \approx 4 k$) the total link (transducers + chip) efficiency is $\sim 0.838 \times 0.47 \approx 0.4\%$.

Fig. 8 shows the key waveforms of the proposed power management during start-up when the external power Tx voltage (V_S) was suddenly increased from zero to 8.5 V_{p-p} (peak-to-peak). As shown in Fig. 8, V_L was first quickly charged to 1.6 V in a passive manner at which the chip became fully functional and charged V_L to 3 V with self-regulation.

Fig. 9 shows the measured waveforms for the self-regulated power management in response to a sudden increase in the transmitted power (proportional to power Tx voltage, V_S). In Fig. 9a, when V_S was increased from 11 V_{p-p} to 18 V_{p-p}, the chip adaptively adjusted the width of S pulses to maintain V_L constant at 3 V with more frequent reverse currents. As shown in the zoomed waveforms in Fig. 9b, since the power Rx transducer has a large impedance of $\sim 5 k \Omega$ at 1 MHz, limiting reverse current, at high V_S of 18 V_{p-p} the chip even kept M_2 on (S : low) for several power-carrier cycles to load the transducer with C_L and limit the received power, regulating V_L at 3 V. Fig. 9 also shows the proper operation of the voltage doubler by providing a DC shift across V_P . At $V_L = 3 V$, V_L ripples and line regulation were measured 3.4 mV and 0.23%, respectively.

Fig. 10 from top to bottom shows the measured modulated V_P , Tx_EN_0 , Tx_EN_1 and transmitted data pulses (Tx Data). In this measurement, V_P was modulated for both IDs “0” and “1”. When $addr = 1$ (only activation notch) was detected, the Gastric Seed with ID “0” was enabled (Tx_EN_0 : high) to transmit data pulses and vice versa.

Fig. 11 shows measured pulse-based data transmission (15 bits) at the rate of 75 kbps using a pair of ultrasonic transducers spaced by 3.75 cm inside water, mimicking tissue. The width of each transmitted pulse was ~ 140 ns. The chip power consumption was measured 63 μW and 30 μW with and without data transmission at 75 kbps, respectively, resulting in $(63 \mu W - 30 \mu W) / 75 \text{ kbps} = 440 \text{ pJ/bit}$ energy consumption of the data Tx. Each pulse generated a $\sim 15 \mu s$ voltage ringing at 1 MHz across the Rx data transducer. Since SWs are low frequency (10–500 mHz) signals, in the current prototype with 75-kbps transmission of 15

bits of data and additional 10 bits of address ID for each Gastric Seed, at least ~1000 Gastric Seeds can be operated continuously if each is sampled at 3 Hz.

V. CONCLUSION

The proposed distributed millimeter-sized Gastric Seeds hold the promise of large-scale gastric SW recording with minimal damage. We presented the concept of ultrasonically interrogated Gastric Seeds along with a proof-of-concept power management / data Tx chip. The prototype chip includes a self-regulated power management that performs rectification, regulation and OVP in one step using only one off-chip capacitor as well as an addressable pulse-based data Tx with measured data rate of 75 kbps and energy consumption of 440 pJ/bit using a pair of 1 MHz ultrasonic transducers spaced by 3.75 cm in water. Our future work is to extend the number of Gastric Seeds and demonstrate fully wireless recording capability with a robust ultrasonic interrogation platform.

Acknowledgments

This work was supported in part by the National Institutes of Health under Grant NIBIB-U18EB021789.

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Fig. 1. Conceptual diagram of the proposed Gastric Seed technology for large-scale recording of gastric SWs.

Fig. 2.

Simplified diagram of the proposed Gastric Seed chip interfacing with a pair of stacked power/data ultrasonic transducers.

Fig. 3. Switch controller schematic diagram and key waveforms of the self-regulated mechanism using reverse current.

Fig. 4. Schematic diagram and key operational waveforms of the proof-of-concept addressable data transmitter with IDs “0” and “1”.

Fig. 5.
Gastric Seed chip micrograph occupying 0.6 mm² including pads.

Fig. 6. Measurement setup with ultrasonic transducers perfectly aligned with 3D printed plastic holders.

Fig. 7.

(a) Measured PCE and VCE of the power management at different $R_{L,DC}$. (b) PTE of the ultrasonic link at different $R_{L,AC}$.

Fig. 8.

Measured V_L and V_P waveforms during start-up when external V_S (power Tx voltage) was increased from zero to $8.5 V_{p-p}$.

Fig. 9.

(a) Measured V_L and V_P waveforms when V_S was increased from 11 V_{p-p} to 18 V_{p-p}. (b) Zoomed waveforms of V_L and V_P ($C_L = 10$ μF).

Fig. 10.

Measured waveforms for the pulse-based data transmitter showing how addressable Gastric Seeds (IDs "0" and "1") can be activated.

Fig. 11.
Measured transmitted and recovered data bits at 75 kbps.