Design of a Bone-Guided Cochlear Implant Microsystem With Monopolar Biphasic Multiple Stimulations and Evoked Compound Action Potential Acquisition and Its In Vivo Verification

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Abstract—A CMOS bone-guided cochlear implant (BGCI) microsystem is proposed and verified. In the implanted system on chip (SoC) of the proposed BGCI, the evoked compound action potential (ECAP) acquisition and electrode–tissue impedance measurement (EAEIM) circuit is integrated to measure both ECAP and electrode–tissue impedance for clinical diagnoses. Both positive/negative-voltage charge pumps and monopolar bipolar constant-current stimulation (CCS) stimulator are designed on-chip to realize monopolar bipolar CCS or double-electrode multiple stimulations with a maximum stimulation current of 1.2 mA and a step of 10 µA. With the double-electrode multiple stimulations, the electric field can be shifted and localized under the stimulating electrode to stimulate the auditory nerves. The wireless bilateral data telemetry circuits with a full-wave active rectifier and the pulsed load-shift keying (PLSK) modulators/demodulators are designed for power and data transmission. In vivo animal tests on guinea pigs have shown that the Wave III of electrically evoked auditory brainstem responses (EABRs) can be evoked successfully by electrical stimulation. Moreover, the decreasing latency gradient of evoked Wave III has been measured under the double-electrode multiple stimulations where the location of peak electric field can be shifted to the stimulating electrode in the apical site to stimulate the auditory nerves. Thus, the desired frequency resolution and spatial specificity of stimulation can be achieved. Both electrical measurement and in vivo animal tests have verified that the proposed BGCI microsystem is a feasible solution to eliminate the symptoms for patients with high-frequency hearing loss.

Index Terms—Bone-guided, cochlear implant (CI), evoked compound action potential (ECAP), implantable medical device (IMD), in vivo animal test, stimulator, wireless power and bilateral data telemetry.

I. INTRODUCTION

CO NVENTIONAL cochlear implant (CI) has been successfully used to help patients with serious sensorineural hearing loss by electrically stimulating the auditory nerves through an array of electrodes deployed inside the cochlea [1], [2]. Recently, the bone-guided CI (BGCI) microsystem has been reported [3], [4] as a potential clinical treatment for patients with high-frequency hearing loss while preserving the residual low-frequency hearing. Unlike the conventional CIs, the electrodes of BGCI are placed on the bone surface and round window of the cochlea. Thus, they are less invasive, and the risk of causing meningitis [1] can be reduced significantly.

In this article, a CMOS BGCI microsystem with an implanted System on Chip (SoC) is proposed [5] and designed with key advances over the previous work [3], [4]. The three key advances are evoked compound action potential (ECAP) acquisition and electrode–tissue impedance measurement (EAEIM), monopolar bipolar constant-current stimulation (CCS) with double-electrode multiple stimulations, and wireless power and bilateral data telemetry with higher power conversion efficiency (PCE).

During clinical diagnoses of CIs, the ECAP signal [6] is measured and transmitted out during and after surgery.
to evaluate the effectiveness of electrical stimulation. The electrode–tissue impedance is also measured [7] and transmitted out to check the electrode–tissue contact status. The first advance of the proposed BGCI microsystem is the design and integration of two measurement circuits, called the ECAP EAEIM circuit, on the implanted SoC. Compared to [8] and [9], the proposed EAEIM circuit has the advantages of smaller input-referred noise, shorter recovery time, and full on-chip integration.

In the second advance of the proposed BGCI microsystem, monopolar biphasic CCS with double-electrode multiple stimulations is performed by a monopolar biphasic CCS stimulator circuit. During stimulation, the electrode on the round window is grounded. One of the four electrodes on the cochlea bone is selected to perform the monopolar biphasic CCS with both positive and negative constant currents, whereas the electrode adjacent to the stimulating electrode is also selected to perform the biphasic counter stimulation simultaneously using a current with opposite polarity. It is found that the peak electric field can be shifted and localized under the stimulating electrode on the cochlea bone, rather than under the grounded round-window electrode. Therefore, frequency resolution and spatial specificity of stimulation can be enhanced [10]. This allows the customization of individual treatment [11] for different patients to compensate for their individual bands of hearing loss with electrical stimulation. Moreover, both positive and negative stimulus currents are adjustable up to 1.2 mA with a smaller step of 10 μA/step. Thus, the location of the peak electric field in the cochlea can be more precisely controlled by the stimulators to achieve a higher frequency resolution and spatial specificity.

In the third advance of the proposed BGCI microsystem, a wireless power and bilateral data telemetry circuit through a pair of coils in 13.56 MHz is designed by using a full-wave active rectifier with delay compensation [12] and a switched-capacitor (SC) power converter [13] to achieve a higher PCE. Moreover, the pulsed load-shift keying (PLSK) backward telemetry is adopted to reduce the power transmission loss during data transmission. Compared to the half-wave structures in [3], [4], and [14]–[17], the reverse current can be minimized to increase PCE. The overall PCE at the output power of 50 mW is increased by 14.7%, whereas the PCE of the rectifier during data transmission is increased by 21.4% compared to those in [4] at the output power of 25 mW. Therefore, the total power consumption of implanted SoC can be reduced by 6.15 mW.

In vivo animal tests on guinea pigs show that the auditory nerves can be successfully evoked by the electrical stimulation of the proposed BGCI microsystem. Moreover, by applying double-electrode multiple stimulations, the location of the peak electric field can be shifted to the stimulating electrode. Thus, frequency resolution and spatial specificity of stimulation can be enhanced.

This article is organized as follows. Section II describes the system architecture and circuits of the proposed BGCI microsystem. Results of electrical measurement and in vivo animal tests are shown in Section III. Finally, a conclusion is drawn in Section IV.

II. ARCHITECTURE AND CIRCUITS

Fig. 1 shows the overall architecture of the proposed BGCI microsystem, where both the external unit and implanted SoC are coupled through a pair of coils. All the blocks in Fig. 1, except acoustic digital signal processor (DSP), acoustic signal acquisition circuit, binary phase shift keying (BPSK) modulator/demodulator, and low dropout (LDO) regulators, have been designed to obtain performance advances over the previous work [4]. The implanted SoC includes the proposed EAEIM circuit and monopolar biphasic CCS stimulator with positive/negative-voltage charge pumps (CPs) [18], [19]. The wireless power and bilateral data telemetry circuit is also designed by using the proposed full-wave active rectifier and SC power converter, integrated with LDOs, a class-E power amplifier, and data modulators/demodulators. The power of implanted SoC is supplied from the external unit wirelessly through coils. Both measured ECAP signals and electrode–tissue impedance data are transmitted with 13.56-MHz carrier frequency from the implanted SoC through the secondary coil and the primary coil to the external unit by PLSK backward telemetry.

The external unit includes an acoustic signal acquisition circuit and an acoustic DSP [3], [4]. In the external unit, the acoustic signals are amplified and digitized by an acoustic signal acquisition circuit. Then, the digitized signal is processed by an acoustic DSP to obtain the desired stimulation patterns corresponding to the frequency range of hearing loss. Both patterns and commands are further processed and transmitted with a 13.56-MHz carrier frequency through the primary coil and the secondary coil to the implanted SoC by BPSK forward telemetry.

There are two operating modes in the proposed BGCI microsystem, namely, the diagnostic mode and the normal operation mode. In the diagnostic mode, the EAEIM circuit is enabled to measure the ECAP signal in the ECAP measurement phase and the electrode–tissue impedance in the impedance measurement phase. In the normal operation mode, monopolar stimulation or double-electrode multiple stimulations are performed.

A. ECAP Acquisition and Electrode–Tissue Impedance Measurement Circuit

As shown in Fig. 2(a), the EAEIM circuit consists of input protection circuits (IPCs), a capacitively coupled chopper instrumentation amplifier (CCCIA) [20], [21], an EAEIM circuit [7], SC low-pass filter (LPF) and amplifier [20], and a 10-bit successive approximation register (SAR) analog-to-digital converter (ADC) [20], [21]. The CCCIA with chopper modulation is used to suppress flicker noise and amplify the ECAP signal with a gain of 46.6 dB. The ripple reduction loop (RRL) is adopted in the CCCIA to reduce chopper-induced ripples. The hybrid dc servo loop (HDSL) that is composed of a digital DSL and an analog DSL is applied to eliminate the electrode dc offset with fast settling time [20], [21]. To filter out high-frequency noise and residual chopping ripples, a high-linearity first-order SC-LPF is used. The SC amplifier (SC-Amp) for signal amplification is also
integrated to drive the capacitor array of SAR ADC and provide a programmable gain $A_V$ of 12.8/22.7/32.2 dB.

The equivalent electrode–tissue circuit model is also shown in Fig. 2(b) where its simplified circuit of $R_{\text{total}}$ and $C_{\text{total}}$ is also shown on the right-hand side. In the EAEIM circuit, a differential current switch with switching frequency $f$ is used to inject an accurate step current $I_{\text{IMP}}$ into the electrode–tissue interface and generate a voltage accordingly, as shown in Fig. 2(a). The common-mode feedback (CMFB) bias circuit is adapted to stabilize the common-mode bias [7]. A high-pass filter is used to eliminate the dc offset and a buffer to eliminate the loading effect to the SC LPF. Moreover, the impedance measurement circuit shares SC LPF, SC-amp, and 10-bit SAR ADC with the ECAP acquisition circuit in the implanted SoC. Thus, power dissipation can be reduced.

According to [7], $R_{\text{total}}$ and $C_{\text{total}}$ of Fig. 2(b) can be expressed as $R_{\text{total}} = R_s + R_{\text{bone}}$ and $C_{\text{total}} = C_{\text{dl}}$ in series with $C_{\text{bone}}$. Their values can be extracted from $\Delta V$ and slope of $V_{\text{SCP}} - V_{\text{SCN}}$ at the output nodes of SC-Amp in Fig. 2(a) as

\[
\Delta V = 2(I_{\text{IMP}}R_{\text{total}})A_V
\]

\[
\text{Slope} = \frac{I_{\text{IMP}}}{C_{\text{total}}}A_V.
\]

The total electrode–tissue impedance $Z_{\text{total}}$ can be calculated as

\[
Z_{\text{total}} = R_{\text{total}} + \left(\frac{1}{2\pi f C_{\text{total}}}\right).
\]
is bypassed, and the differential current switch is connected to both electrode of the selected channel and round-window electrode with the switch Sr1 OFF to perform the EAEIM. During the ECAP recording sub-phase in the diagnostic mode, as shown in Fig. 3(b), a recovery time of 40 μs is required to decrease the switch transient before ECAP signal acquisition of CCCIA. After the recovery time, ECAP is recorded by the EAEIM circuit through the simulated electrode and the grounded round-window electrode with Sr1 ON.

Both the acquired ECAP signal and impedance data are transmitted out from the implanted SoC through coils. The external unit can then decode and obtain the ECAP signal and impedance data.

B. Monopolar Biphasic CCS Stimulator and Double-Electrode Multiple Stimulations

As shown in Fig. 1, the proposed monopolar biphasic CCS stimulator is composed of two 7-bit current DACs, two biphasic pulse generators, a reference generator, and a four-channel current driver [22], [23]. The circuit schematics of the biphasic pulse generator, four-channel current driver, and discharge switch are shown in Fig. 4(a)–(c), respectively, where stacked transistors are used to avoid voltage overstress problems. High-voltage power supplies of +6 and −6 V are required for anodic pulses and cathodic pulses, respectively. Thus, positive- and negative-voltage CPs [18] are also integrated into the implanted SoC to provide the required voltages for the stimulator, as shown in Fig. 1. In the monopolar biphasic CCS stimulator of Fig. 1, control signals, AMP1[6:0] and AMP2[6:0], are sent to 7-bit current DACs to generate the required stimulus current levels with 7-bit resolution, whereas CH_SEL[1:0] is used to select one of the four channels for stimulation. The control signal, MULTI_CH, is used to choose between the monopolar stimulation phase and the double-electrode multiple-stimulation phase. Control signals, ANO and CAT, shown in Fig. 3(b) are used to enable anodic and cathodic stimulations, respectively.
In the monopolar stimulation phase, as shown in Fig. 5(a), the monopolar biphasic CCS is realized by sending positive and negative constant currents from the biphasic pulse generator 1 to the single electrode selected by CH_SEL[1:0] on the cochlea bone surface with the electrode on the round window grounded to inject charges into the auditory nerves. The monopolar biphasic CCS is performed successively for each electrode on the bone surface. The deselected electrodes remain at the high impedance state to minimize leakage currents.

The discharge operation is required to reduce the residual charge in the electrode–tissue interface after biphasic CCS. Thus, safety requirements can be guaranteed [23]. The circuit schematic and control signals of discharge switches SW1–SW4 integrated into each channel, as shown in Fig. 4(b), are shown in Fig. 4(c). It can be seen that the gate voltages $V_{DIS-P}$ and $V_{DIS-N}$ are biased so that $M_{DIS-P}$ and $M_{DIS-N}$ are turned off during the positive/negative stimulation phases and turned on during the discharge phase. The longer discharge time of 490 $\mu$s than that in ECAP acquisition is chosen to make the residual charge lower than the safety requirement. Since the electrode voltage $V_{CH}$ could be either positive or negative depending on the directions of stimulus currents, the cascode structure $M_{DIS-P}$ and $M_{DIS-N}$ can prevent the two MOS devices from voltage overstress issues.

In the double-electrode multiple-stimulation phase, as shown in Fig. 5(b), another electrode adjacent to the stimulating electrode is selected to provide a counter stimulation using a current with opposite polarity and adjustable current. For example, both CH1 and CH2 are selected to stimulate simultaneously with opposite currents during $t_1$. The operation is repeated for other pairs of channels during $t_2$ and $t_3$. This allows the electric field to be localized under the stimulating electrode, which can enhance both frequency resolution and spatial specificity of electrical stimulations.

With two 7-bit current DACs and two biphasic pulse generators, stimulus currents $I_{ANO1}/I_{CAT1}$ and counter stimulation
currents $I_{AN02}/I_{CAT2}$ with 7-bit resolution can be generated to drive two adjacent electrodes with two different current levels and polarities simultaneously. As shown in Figs. 4(a) and 5(b), the current paths of CH1 are selected by control signals AN01/CH1 for $I_{AN01}/I_{CAT1}$ and AN02/CH1 for $I_{AN02}/I_{CAT2}$. For instance, when CH 1 and CH 2 are selected to perform the double-electrode multiple stimulations, $I_{AN01}$ and $I_{CAT1}$ are selected to flow into the current driver of channel 2 as the stimulation current, whereas $I_{AN02}$ and $I_{CAT2}$ are selected to flow into the current driver of channel 1 as the counter stimulation current. Thus, the double-electrode multiple stimulations can be realized.

To analyze the electrical field distribution of double-electrode multiple stimulations, the finite element model (FEM) of cochlea based on [24] is adopted, as shown in Fig. 6, where the cochlea is extruded to form a linear model. It is shown from the electromagnetic (EM) stimulation that, under CCS, the electric fields can pass through cochlear bone and membranes to stimulate auditory nerves. The electric field distributions of the basilar membrane are shown in Fig. 7 where the membrane is unfolded into a rectangular shape. As shown in Fig. 7, the stimulation current (I_{stim}) at CH2 is 500 $\mu$A, and the counter stimulation current (I_{stimC}) is applied at CH1. By increasing the counter stimulation current from 0 to 300 $\mu$A, the intensity of the electric field at the base is decreased since it is canceled out by the counter stimulation current. Moreover, the location of the peak electric field is shifted from the basal electrode CH1 toward the apical electrode CH2, and auditory nerves under CH2 can be stimulated when applying the double-electrode multiple stimulations. Without the counter stimulation, the peak electric field would be located under the CH1, and the stimulations at different electrodes could not obtain spatial specificity and frequency resolution. With the double-electrode multiple stimulations, both desired frequency resolution and spatial specificity can be achieved.

Theoretically, the symptoms of patients with hearing impairment at different frequencies can be eliminated through monopolar biphasic CCS with double-electrode multiple stimulations. However, under normal surgical operation, it is difficult to put extra electrodes close to the apex site of the cochlea. Thus, the hearing impairment at other frequencies below 2000 Hz could not be eliminated.

C. Wireless Power and Bilateral Data Telemetry Circuit

The block diagram of wireless power and bilateral data telemetry circuits is shown in Fig. 8, where the external part is linked with the implanted part through coils. The external control part consists of a class-E power amplifier [12], a BPSK modulator [4], [16], [17], and a PLSK demodulator [12]. The implanted part includes a full-wave active rectifier [12], an SC power converter [13], three LDOs (ALDO for analog circuits, DLDO for digital circuits, and RLDO for reference voltage of ADC), a BPSK demodulator [4], [16], [17], and a PLSK modulator [12]. The ac signal received from the external control part is regulated by a full-wave active rectifier. The regulated 3.3 V ($V_{REC}$) provides the supply voltage of CPs and is connected to an SC power converter for further regulation. A 2/3 step-down conversion structure is used in the SC power converter to generate a 2-V output voltage for LDOs so that the voltage dropout between LDOs output voltages 1.8 V and $V_{REC}$ (3.3 V) can be minimized.

The control signals and circuit schematic of the SC power converter are shown in Fig. 9(a) and (b), respectively. When $\Phi_1$ and $\Phi_{1H}$ are high, $M_{SC1}$, $M_{SC4}$, $M_{SC5}$, and $M_{SC7}$ are turned on. $V_{C1} = V_{C2} = V_{REC} - V_{OUT}$. Alternatively, when $\Phi_2$ and $\Phi_{2H}$ are high, $M_{SC2}$, $M_{SC3}$, and $M_{SC6}$ are turned on. $V_{C1} + V_{C2} = V_{OUT}$. As a result, $V_{OUT} = 2/3 \times V_{REC}$.

Both digitized ECAP and electrode–tissue impedance data are modulated by the PLSK modulator into a pulse sequence $D_{MOD}$, as shown in Fig. 8. The pulse sequence $D_{MOD}$ greatly reduces the turn-on time of the PLSK switch [12] and mini-
mizes its interference to wireless power transmission compared to the conventional LSK method. This results in a significant improvement in PCE [12] during the PLSK operation. In the PLSK modulator, the resonant capacitor of the secondary coil consists of two capacitors $C_{2a}$ and $C_{2b}$ connected in series. When the PLSK switch is turned on, only $C_{2a}$ is bypassed, and $C_{2b}$ is still connected in parallel with the secondary coil. Thus, both resonant frequency and $V_{\text{in,coil}}$ on the primary coil are changed. $V_{\text{in,coil}}$ is sent to the envelope detector of a PLSK demodulator [12] in the external part. The output signal $E_{\text{out}}$ is generated and sent to LPF and the comparator to generate the demodulated pulse sequence $D_{\text{DEM}}$. Finally, in the clock recovery circuit, a divided-by-64 frequency divider is used to divide the carrier frequency of 13.56 MHz to generate a 211-kHz clock signal.

Furthermore, a BPSK demodulator is implemented in the implanted SoC to receive the stimulation pattern transmitted from the external unit. The BPSK demodulator can demodulate the BPSK data from the external unit without degrading the power transfer efficiency through coils [4], [16], [17].

As shown in Fig. 10(a), the PLSK data include 50 packets. Each packet carries one sampled data generated from the EAEIM circuit. Also, each data packet includes a pseudorandom noise (PN) sequence for synchronization and an appended cyclic redundancy check (CRC) for error checking.

The BPSK packet patterns for the monopolar biphasic CCS stimulator are shown in Fig. 10(b). In each channel, 7 bits ($\text{AMP}[6:0]$) are used to indicate the magnitude of stimulation currents, and 1 bit ($\text{Sign}$) is used for the polarity. Additional 6 bits are included to identify the stimulation duration. The stimulation patterns are decoded and sent to the stimulator to generate the corresponding stimulation current. The Mode bit is used to choose the diagnostic mode or the normal operation mode. In the diagnostic mode, the EN bit is used to choose between the ECAP measurement and the impedance measurement.

III. EXPERIMENTAL RESULTS

Both external unit and implanted SoC of the proposed BGCI microsystem are designed and fabricated in 0.18 μm 1.8 V/3.3 V standard CMOS technology with deep n-well. The photographs of fabricated chips are shown in Fig. 11, where the chip area of implanted SoC (external unit) is 12 mm$^2$ (13.5 mm$^2$). Each circuit block was tested separately, and the function of the whole system was verified in both electrical measurement and in vivo animal tests.
A. Results of Electrical Measurement

The measured frequency response of the amplifier part in the fabricated EAEIM circuit is shown in Fig. 12 where the programmable gain is 59.4/69.3/78.8 dB in the bandwidth of 0.34 Hz–3.07 kHz. To verify the functionality of ECAP acquisition in the EAEIM circuit, a complete ECAP signal was emulated by a signal generator. Since the electrode voltage under the stimulation current for ECAP measurement is always blocked by the IPC, only ±1 V of step electrode voltage was used. A commercial summing amplifier was used to generate the input voltage $V_{IN}$ of IPC in Fig. 3(a) by adding up the emulated ECAP signal and the step electrode voltage. $V_{IN}$ was then sent to CH1 of the EAEIM circuit where the electrode voltage was blocked, and the ECAP signal can be amplified at the output of CCCIA. Fig. 13(a) shows the measured waveforms of $V_{IN}$, $V_{OP}$, $V_{ON}$, and the recorded ECAP signal $V_{OP}$−$V_{ON}$, whereas Fig. 13(b) shows the measured waveforms of SC-Amp output voltages $V_{SCP}$, $V_{SCN}$, and $V_{SCP}$−$V_{SCN}$. It can be seen from both figures that, during the stimulation and discharge time, the IPC can block stimulation voltage and keep a low residual voltage. After the recovery time of 40 $\mu$s, the reconstructed analog ECAP waveform can be obtained, as shown in Fig. 13(b). This verifies the ECAP acquisition function of the fabricated EAEIM circuit.

In the impedance measurement phase, the CCCIA is bypassed, and the EAEIM circuit is activated, as shown in Fig. 2(a) where the voltage gain $A_V$ and the sampling frequency of the SC-Amp are 41.06 V/V and 105.5 kHz, respectively. The equivalent electrode–tissue circuit model in Fig. 2(b) was realized by discrete RC components for impedance measurement. The injected step current $I_{IMP}$ is 0.775 $\mu$A with the switching frequency $f$ of 125 Hz. The resultant voltage across the discrete equivalent electrode–tissue circuit is amplified by the SC-Amp. The measured output voltage ($V_{SCP}$−$V_{SCN}$) is shown in Fig. 14 where the sharp voltage change $\Delta V$ is 263 mV and the average slope is 668.5 V/s.

From (1) to (3), the extracted values of $R_{total}$, $C_{total}$, and $Z_{total}$ are 4.13 K$\Omega$, 47.6 nF, and 30.88 K$\Omega$, respectively. Compared to the RC values in Fig. 2(b) and its calculated $Z_{total}$ = 29.46 k$\Omega$, the extraction errors of $R_{total}$, $C_{total}$, and $Z_{total}$ are 3.3%, 4.80%, and 4.82%, respectively. Thus, the accuracy of the impedance measurement circuit is acceptable for checking the electrode–tissue contact status.

In the normal operation mode, the received 55-bit packet pattern is decoded to generate currents for the monopolar biphasic stimulation or the double-electrode multiple stimulations on four electrodes. The total required time is 1.33 ms, which is corresponding to the maximum stimulation rate of 3000 pulses per second (pps). Fig. 15(a) and (b) shows the measured waveforms of electrode output voltages under monopolar biphasic stimulation and double-electrode multiple stimulations, respectively, where the electrodes are connected with the equivalent electrode–tissue circuit model in Fig. 2(b) and the currents of stimulation and counter stimulation are 400 $\mu$A. In the monopolar stimulation phase, as shown in
Fig. 15. Measured waveforms of electrode output voltages of the monopolar biphasic stimulator in (a) monopolar stimulation phase and (b) double-electrode multiple-stimulation phase. The electrodes are connected by the equivalent electrode–tissue circuit model in Fig. 2(b) [5].

Fig. 16. Measured waveforms of electrode output voltages of the monopolar CCS stimulator with the equivalent electrode–tissue circuit model in Fig. 2(b) as load and under different stimulus currents from 160 $\mu$A to 1.2 mA.

The measured waveforms of electrode output voltages of monopolar CCS stimulator with the equivalent electrode–tissue circuit model in Fig. 2(b) as load are shown in Fig. 16 where the stimulation currents are adjustable up to 1.2 mA that is close to the simulated value of 1.25 mA. If the electrode–tissue impedance is smaller, 1.25 mA can be delivered. Note that the voltage waveform in Fig. 16 is slightly saturated at around $-6$ V when the monopolar CCS stimulator delivers a 1.2-mA stimulus current. This is because $-6$ V is the most negative voltage that the fabricated negative-voltage CP could provide.

The measured PCEs and output voltages of the fabricated positive-voltage CP and negative-voltage CP are illustrated in Fig. 17(a) and (b), respectively. It is seen that, under the maximum load current of 2.5 mA, the output voltages of positive (negative) voltage CP can be regulated at $+5.953$ V ($-5.872$ V). Under different load currents, PCE can be maintained at above 60% (48%) for the positive (negative)-voltage CP. The measured peak PCE of positive (negative)-voltage CP is 74.0% (56.2%).

The measurements on the wireless power and bilateral data telemetry circuits were performed to verify their functions. The measured PCE of the full-wave active rectifier is 90.1% under the output power of 50 mW. The measured waveforms of PLSK input data, PLSK demodulated data, and $V_{in}$ of the primary coil are shown in Fig. 18(a), whereas those of BPSK input data, BPSK demodulated data, and $V_{C1}$ of the secondary coil are shown in Fig. 18(b). The measured maximum PLSK data rate is 340 Kbps. The PCE of full-wave active rectifier during the PLSK data transmission is 85.2%, which is 21.4% higher than that during the conventional LSK data transmission [3], [4].
The measured performance summary of the proposed BGCI microsystem is given in Table I where comparisons with those of the conventional CIs [1], [2] and the previous work [4] are also given. From Table I, it can be seen that, compared with the previous work [4], the proposed BGCI microsystem has the abilities to record ECAP signal, measure electrode–tissue impedance, perform monopolar biphasic CCS or double-electrode multiple biphasic CCS with a higher current resolution of 10 μA/step, and achieve lower total power consumption of the implanted SoC. Thus, under monopolar biphasic CCS with double-electrode multiple stimulations, the location of the peak electric field in the cochlea can be more precisely controlled by the stimulators to achieve a higher frequency resolution and spatial specificity.

The performance comparison of the EAEIM circuit with the prior work [8], [9] is listed in Table II. It is shown that the ECAP acquisition part of the EAEIM circuit has a lower input-referred noise and a shorter recovery time compared to those in the prior work [8]. Moreover, in the impedance measurement part, the chip area and power consumptions are 0.036 mm² and 5.37 μW, respectively, which are lower than those in [9]. This is because most of its building blocks share with those of the EAEIM circuit in the implanted SoC.

Performance comparison of the proposed wireless power and bilateral data telemetry circuit with those in [4] and [14] is listed in Table III. It can be seen from Table III that the proposed circuit has the highest overall PCE, maximum PCE of the rectifier, and the PCE of rectifier during data transmission among previous works [4], [14] for implantable medical devices (IMDs). The overall PCE at output power $P_{\text{OUT}} = 50 \text{ mW}$, including SC power converter and LDOs, is increased by 14.7% and the PCE of rectifier during PLSK data transmission increased by 21.4% compared to those in [4] at the output power of 25 mW. Therefore, the total power consumption of implanted SoC is reduced to 34.96 mW, which is 15% better than that in [4].
B. Results of in Vivo Animal Tests

The measurement setup of in vivo animal tests on guinea pigs with the proposed BGCI microsystem is shown in Fig. 19(a). Since the size of cochlea bone in guinea pigs is small, only two electrodes CH1 and CH2 are placed on the bone surface of the cochlea, while one electrode is placed at the round window in the in vivo animal test to verify the functions of the proposed BGCI microsystem. In order to fit into the cochlea bone of guinea pigs, electrodes were designed with 1-mm length, 0.4-mm width, and 50 μm thickness, as shown in Fig. 19(b), where the anatomy of the ear of guinea pig and the placement of electrodes are also shown.

The computer delivers a command sequence to the electrically evoked auditory brainstem response (EABR) system and the proposed BGCI microsystem. Then, the EABR system triggers the BGCI microsystem to generate biphasic stimulation currents for a single channel to perform monopolar biphasic CCS or two channels to perform double-electrode multiple stimulations. After electrical stimulations were performed, the EABR waveforms were recorded by the EABR system (Intelligent hearing system, model Opti-Amp8002), which is a commercial device commonly used for hearing tests [3], [4], [18], [22]. The final recorded data were obtained by averaging 200 sets of valid measurement data. The recorded EABR waveform has a series of six to seven vertex positive waves of which I through V vertex positive waves are evaluated. As in [4], the third vertex positive wave called the Wave III is selected in this article as an indication to identify whether the auditory nerves have been successfully activated.

In the animal tests of double-electrode multiple stimulations, different current levels from 0 to 400 μA were applied to CH1 to perform the counter stimulation, while a fixed biphasic CCS current of 500 μA was applied to CH2 to perform the stimulation. The recorded EABR waveforms are shown in Fig. 20 where the Wave III of EABR waveforms with and without counter stimulations can be clearly seen. The latency of Wave III in the recorded EABR waveforms is defined as the time span between stimulus onset point and the peak of Wave III, as indicated in Fig. 20. The latency of Wave III is approximately 2 ms, as reported in [25] and [26]. Since both latencies and morphologies of nerve responses are similar to those in the previous studies [25]–[27], it is verified that the proposed BGCI microsystem can successfully stimulate and activate auditory nerves either in monopolar biphasic CCS with zero current at CH1 or the double-electrode multiple stimulations with 100–300 μA counter stimulation currents at CH1.

**TABLE III**

<table>
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<th>[4]</th>
<th>[14]</th>
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<td>1X/2X Half-wave Rectifier &amp; LDO</td>
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</tr>
<tr>
<td>PCE of Rectifier During Data Transmission</td>
<td>85.2%</td>
<td>63.8%</td>
<td>N/A</td>
</tr>
<tr>
<td>Overall PCE</td>
<td>73.7% @ Pout=50 mW</td>
<td>69% @ Pout=25 mW</td>
<td>69.1% @ Pout=40 mW</td>
</tr>
</tbody>
</table>

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results in Fig. 7(b) where the peak intensity of the electric field is decreased as the counter stimulation current at CH1 is increased. The decrease of peak electric field leads to the decrease of the peak amplitude of Wave III.

The measured latencies of evoked Wave III on EABR waveforms versus different counter stimulation currents at CH1 are shown in Fig. 21 where three fixed currents of 400 (Case 1), 500 (Case 2), and 600 μA (Case 3) are applied to CH2 as the monopolar biphasic CCS. In Fig. 21, the mean latency values measured in animal tests of five guinea pigs are indicated by dots, whereas the standard deviation values are represented by vertical error bars. The results of Fig. 21 show that the mean latencies of Wave III are decreased with the increasing counter stimulation currents. Previous studies on the conventional CI have shown that the measured latencies of evoked Wave III by the stimulations at electrodes from basal sites to apical sites are decreased with a latency decreasing gradient [28], [29]. Thus, the latency decreasing gradient of evoked Wave III, as observed in Fig. 21, indicates that the location of the peak electric field has been shifted from the basal electrode (CH1) toward the apical electrode (CH2) through the double-electrode multiple stimulations. The shift of peak electric field is consistent with the EM stimulation of the electric field distributions shown in Fig. 7(b).

With the verification of animal tests, it is shown that the double-electrode multiple stimulations of the proposed BGCI microsystem can make the peak electric field shift to the stimulating electrode so that the auditory nerves under that electrode can be stimulated. Therefore, the desired frequency resolution and spatial specificity can be achieved.

IV. CONCLUSION

The proposed BGCI microsystem with monopolar biphasic CCS capable of double-electrode multiple stimulations, ECAP acquisition/EAEIM, and wireless power and bilateral data telemetry has been proposed and designed. With the EAEIM circuit in the implanted SoC, both ECAP signal and electrode–tissue impedance can be measured and transmitted out through coils to the external unit for clinical diagnoses on stimulation effectiveness and electrode–tissue contact, respectively. Both positive-/negative-voltage CPs and monopolar biphasic CCS stimulator were designed on-chip to realize either monopolar biphasic CCS or double-electrode multiple stimulations with a maximum stimulation current of 1.2 mA and a step of 10 μA. With the double-electrode multiple stimulations, the electric field can be localized under the stimulating electrode to stimulate the auditory nerves so that the desired frequency resolution and spatial specificity can be achieved. The localization of electric field under the stimulating electrode has been verified through EM stimulations.

In the implanted SoC, the stimulation patterns and commands are generated and transmitted from the external unit to the implanted SoC through the wireless power and bilateral data telemetry circuit with a pair of coils operated at 13.56 MHz. The adopted PLSK backward data transmission has a maximum data rate of 340 Kb/s. The designed full-wave active rectifier can deliver output power up to 100 mW with
the measured PCE of 90.1% and 85.2% when transmitting power and PLSK data simultaneously.

In vivo animal tests on guinea pigs have been performed and the Wave III of EABR responses were evoked successfully by the electrical stimulation generated from the proposed BGCI microsystem. Moreover, it has been verified that, by applying the double-electrode multiple stimulations, the location of the peak electric field can be shifted to the stimulating electrode so that the auditory nerves under that electrode can be stimulated. Thus, the desired frequency resolution and spatial specificity of stimulation can be achieved.

Through both electrical measurement and in vivo animal tests, the functions of the BGCI microsystem have been verified successfully. It has been shown that the proposed BGCI is a feasible solution to eliminate the symptoms for patients with high-frequency hearing loss while preserving the residual low-frequency hearing.

REFERENCES

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