An Implantable Battery System for a Continuous Automatic Distraction Device for Mandibular Distraction Osteogenesis

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Distraction osteogenesis is a method of generating new bone formation by the gradual application of tensile stress across an osteotomy site (a complete cut through the bone). Internal or intraoral distraction devices have become the most common clinical apparatus in craniofacial distraction osteogenesis, although actuating the distraction devices relies upon manual length adjustment under patients' compliance, introducing inconvenience and potential error in the procedure. To realize a fully implantable automatic distraction device, we propose a device design comprising a continuous miniature motor-driven distractor with a controller and an on-board lithium-ion battery. A benchtop prototype was fabricated to demonstrate the device's structural design capable of transmitting sufficient loads with sufficient strain accuracy; it is capable of using a battery selection algorithm to determine an appropriate electrochemistry, temperature, sealability, and form factor and a control algorithm and a testing protocol with a laboratory-fabricated control circuit. This new distraction osteogenesis device enables completely automated and continuous distraction by the application of a low strain magnitude with multiple steps potentially leading to enhanced osteogenic activity.
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1 Introduction

Distraction osteogenesis (DO) is a surgical method of stimulating new bone formation in a controlled fashion by the application of gradual tensile stress across a bisected bone or osteotomy site. Since the clinical technique was first applied to craniofacial implications in 1992 by McCarthy et al. [1], most subsequent researches have focused on developing more effective distractions via empirical examination with a variety of clinical parameters such as latency period, distraction rate, and distraction frequency [2–4]. The main problems of external devices include the unsightly scar formation and infection due to the transcutaneous pins and the lack of acceptance by the patients. Overcoming these limitations, internal or intraoral distraction devices have been developed to become the most common clinical apparatus in craniofacial DO [2]. In both external and internal devices, however, the actuation of the distraction process relies upon manual length adjustment under patients' compliance, introducing inconvenience and potential error in the procedure. More importantly, the continuous distraction process applying low strain magnitude with multiple steps, which leads to greater osteogenic activity and more mature bone formation [4,5], is restricted by the manual operation protocol, which limits the distraction frequency under two to four times per day. These limitations of current techniques motivated the development of the next generation of devices for DO. The continuous automatic distraction concept will lead to minimizing scar formation and infection, providing more acceptable protocols to patients, and accelerating bone regeneration during DO.

In the past a few years, various actuation mechanisms have been proposed to achieve automated distraction, including electric motor, shape memory alloy, and hydraulic pump [6–10]. A comparison of these mechanisms shows that electric motor offers suitable controllability, specific actuation power/energy, and biocompatibility, as given in Table 1. The concept of continuous DO was developed in earlier studies to develop automatic distraction devices including those by Schmelzeisen et al. [6] and Ploder et al. [7], who examined the feasibility of a motor-driven distraction mechanism by animal experiments. In both studies, an electric motor-gearing actuator was used in accordance with separately implanted power units consisting of commercial lithium batteries and control modules. Although these previous studies showed promising results with considerable distraction lengths, they were limited to the experimental level by failing to proceed to human clinical application, mainly due to the excessive size of the device and the power supply. It is important to note that power supplies from both studies occupied a significantly large fraction, at least 50% of the total device size. Thus, the minimization of the total size of implantable devices inevitably requires optimizing the battery design and/or selection, which is the main issue of this paper.

Recently fast-developing microbattery technology might answer to this demand by providing high power/energy density with flexible shapes such as thin film lithium batteries and also by satisfying environmental requirements. As summarized in Table 2, implantable batteries in other medical applications and their design strategies have been studied, including cardiac pacemaker, defibrillator, neurological stimulator, and drug pump [11–15], providing general considerations in selecting a battery for the present application. Compared with the other medical devices, the present application requires a significantly higher power density within a relatively short lifetime, allowing real-time performance testing. In this paper, we present the interdisciplinary design processes for a continuous automatic distractor and the preliminary results including structural design and controls architecture, focusing on strategies for choosing power supplies to the implantable medical system via a MATLAB based battery selection algorithm [16,17].

2 Methods

2.1 Structural Design and Control Scheme. Based on the literature and current battery technology, functional requirements and environmental constraints of the implantable distraction device are chosen as follows:

(1) minimum output distraction force $F=42$ N [18–20]
(2) distraction rate or linear actuator speed $S=1$ mm/day [2]
(3) maximum distraction length $L=15$ mm [2,21]
(4) thickness <10 mm; also minimum total size is desirable (reference size: $15\times15\times60$ mm^3 [6,7,22])
(5) operating temperature $=37\,^{\circ}$C (under a critical temperature of $37.8\,^{\circ}$C [23])

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Table 1 Comparison of actuation mechanisms for continuous distraction [6–10]

Functional/environmental requirements						
Mechanism	Force output	Accuracy	Resolution	Actuation energy density	Size	Biocompatibility
EAP	<15 N	High ($<1\times10^{6}$ m)	Medium	3.4 J/cm^3	$6\times6\times65$ for 8 mm	Low (high voltage ~100 V/mm)
Shape memory alloy	10–40 N	Medium ($<1\times10^{3}$ m)	Low	3.12 J/cm^3	$1.2\times40\times40$ for 10 mm	Low (high temperature 47–80°C)
Hydraulic pump	<45 N	Medium ($<1\times10^{3}$ m)	Medium	External syringe driver	$10\times10\times55$ for 25 mm	Medium
Electric motor	0.25–3.0 mN m (transmissible)	Medium ($<1\times10^{3}$ rad)	High	11.8–118 J/cm^3	$6\times6\times10$ ~$10\times10\times25$	Medium

Table 2 Common application and batteries for implanted medical devices (data taken from Refs. [7,8])

Implanted device	Typical electrochemistry	Power requirements (mW)	Energy density[a] ((W h/l)$^{-1}$)	Lifetime requirements
Pacemaker	Li/I_2	0.030–0.1	700	>10 years
Defibrillator	Li/SVO	10,000	780	Several years
Neurological stimulator	$Li/SOCl_2$	0.3 to several	680	>5 years
Drug pump	$Li/SOCl_2$	0.1–2	680	>5 years
Present application	–	50–500	222	15–20 days

[a]For 37°C, under favorable discharge conditions.

(6) nominal voltages of 1.2–3.7 V, low current drain as possible [24]
(7) All materials must be biocompatible or sealed.

A commercial miniature dc motor with a planetary gearhead (series 0615, Faulhaber MicroMo Inc., Clearwater, FL) has been selected for an actuation system for the device along with a rotary-to-linear mechanism by using a lead screw and a miniature thrust bearing (Fig. 1), resulting in the average linear distraction force of 57 N and the maximum distraction length of 15 mm. The planetary gearhead mechanism can provide a 4096:1 speed reduction to make low speed as 6 mm/min, which eventually can be reduced to 1 mm/day distraction rate by additional circuit design to control the actuation.

Clinically, distraction protocols are divided into the latency period (time period between osteotomy and initiation of distraction), the rate and rhythm of distraction (amount and frequency of operational movement), and the maturation period (period of time the patient is maintained in rigid fixation). In this study, we focused on several aspects of the DO protocols pertaining to the rate and rhythm studied for our preliminary design of a continuous automated device. The dc motor speed and the corresponding distraction rate can be controlled intermittently by pulsed power input from the control circuit, including a clock-counter and a logic gate. A schematic diagram for the control circuit is shown in Fig. 2, and its electric components are listed in Table 3. The width of a pulse T_1 is determined by the resistor-capacitor (RC) oscillator within a binary clock-counter (Fairchild Semiconductor, South Portland, ME), which drives the clock input with frequency f by the following relationship:

$$f = \frac{1}{2.2 \times R_1 \times C_1} = \frac{4}{T_1} \tag{1}$$

and the interval of the pulses T_2 is dependent upon the pin-connections of the clock-counter into the logic gate. Thus, by simply changing the composition of the passive components and their connectivity, the power pulse can be modulated to generate different distraction parameters such as distraction rate and frequency. For example, the most successful distraction protocol from the previous clinical and experimental studies (the distraction rate of 1 mm/day with multiple steps) can be achieved. Signal measurement using an oscilloscope can verify the power pulse modulation for a certain protocol before the custom printed circuit board (PCB) circuit fabrication.

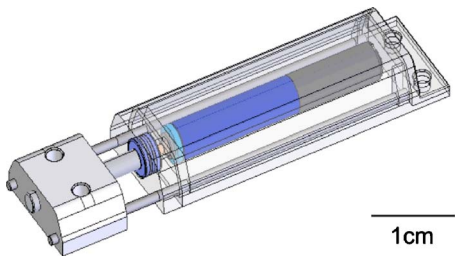

Fig. 1 Structural design using SolidWorks®2006 with transparent view

2.2 Power/Energy Requirements and Battery Selection. Selection of optimal battery for the automatic distractor required an accurate measurement of power and energy consumption with realistic operation protocol during DO. Programmable charging procedures by a battery tester (Solartron Analytical, Hampshire, UK) was used to measure the current drains under a constant voltage of 3.7 V to the actuator connected to a control circuit, and

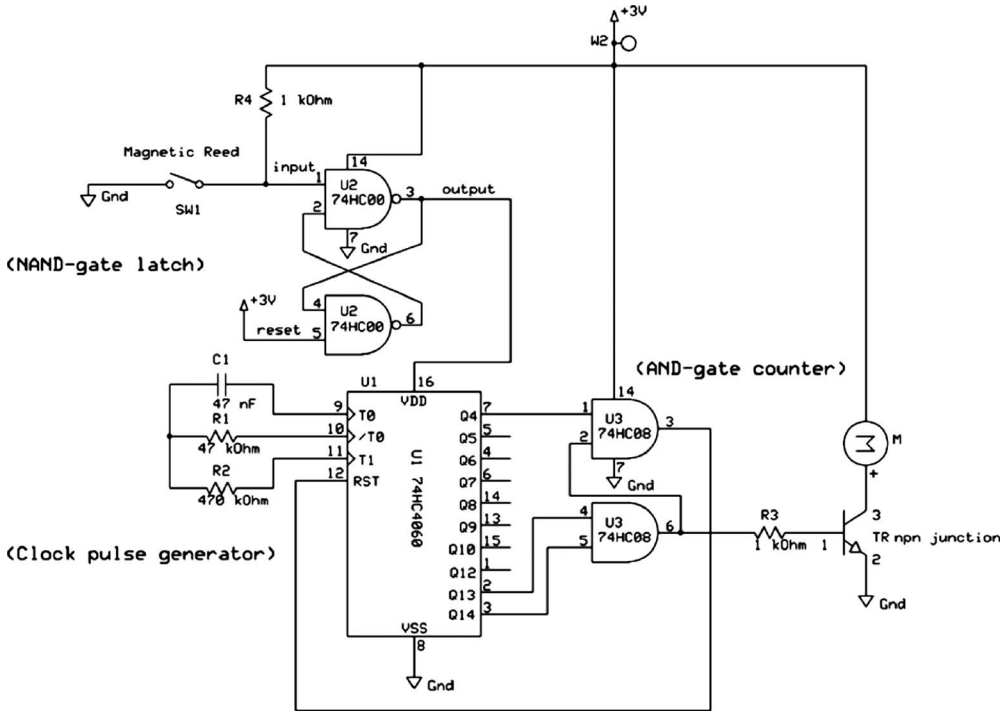

Fig. 2 Schematic diagram for control circuit

we obtained the battery requirements profile including electrochemistry, geometry, and environmental constraints, as shown in Table 4. The electrochemistry includes cell potential, discharge profile, capacity, and lifetime of the battery. The nominal voltage required for the motor operation lead to the cell potential is around 3.7 V, and the current discharge range of 0.15–60 mA with a lifetime of 15 days resulted in the capacity requirement of 70 mA h. Geometric constraints such as volume and surface area were decided based on the structural design (Fig. 1). For example, the volume for the power supply was calculated by subtracting the motor-gearhead volume from the total device volume, resulting in 1120 mm^3. The temperature and the battery operation are mutually dependent for the heat dissipation from battery may increase the temperature, and the high-operating temperature can result in self-discharge of the battery. For the motor selection, we obtained the maximum temperature of 42.2°C from the heat dissipation of the motor operation based on the product specification. However, the actual maximum temperature and its effect on the battery performance must be examined parallel to the safety testing.

The power optimization for wireless energy requirements (POWER) is a MATLAB based battery selection algorithm for wireless micro-electromechanical systems (MEMS) applications developed by previous researchers in our laboratory [16,17]. We used the POWER algorithm to select candidate batteries for the distraction device from the commercial batteries database, including most lithium-based electrochemical systems with various shapes such as cylindrical and prismatic cells. All the input parameters including energy/power requirements and geometrical constraints were entered based on the actual measurement and structural design. Then, the algorithm could recommend the optimal system among the batteries in the database.

2.3 Battery Testing. Following the battery selection, the candidate battery system was tested for the equivalent discharging profile by a complete clinical protocol of distraction osteogenesis. As described in the design criteria, a distraction rate of 1 mm/day was applied for a total distraction length of 15 mm, and the equivalent current discharge for this protocol was applied to the candidate battery to verify its selection under the body temperature. All load-cycle testing was conducted with a battery tester (Maccor, Tulsa, OK) to record the current and voltage of the system, and the body temperature experiments were realized by using a laboratory oven at 37°C. Batteries were fully charged until 4.2 V between each discharging cycle by a constant current mode of C/2 rate.

To simulate an averaged, typical pulse load profile as would be required by clinical DO protocols, a load cycle consisting of a sleep mode current of 150 μA for 150 s followed by a pulse load

Table 3 List of electric components for the control circuit in Fig. 2

Component No.	Value and description	Order code (mouser part no.)
U1	14 stage binary ripple counter with RC oscillator	512-MM74HC4060MTCX
U2	Quad 2-input logic NAND gate	512-MM74HC00MTCX
U3	Quad 2-input logic AND gate	512-MM74HC08MTCX
R1	47.0 kΩ resistor	660-RK73H1JTTD4532F
R2	470.0 kΩ resistor	660-RK73H1JTTD4533F
R3, R4	1.0 kΩ resistor	660-RK73H1JTTD1001F
C1	47.0 nF capacitor	581-CF028B0473J
TR	Junction transistor (NPN-type)	863-MMBT6428LT1G
SW1	Magnetic reed switch	816-R1-80GP0515

Table 4 Battery requirements for electrochemistry, geometry, and environment

Electrochemistry	Device specifications
Cell potential	Nominal voltage=3.7 V
Discharge profile	Current drains=0.15–60 mA (sleep–pulse)
Capacity	>70 mA h
Lifetime	~15 days
Geometry	
Volume	1120 mm^3
Surface area	240 mm^2
Mass	<20 g
Shape	Cylindrical or prismatic
Environment	
Temperature	T≈42.2°C, to be measured
Biocompatibility	Need to be sealed

of 60 mA for 100 ms (time-average current of 190 μA) was applied for 15 days. This testing protocol demonstrated the battery performance to cope with prolonged periods of inactivity along with demanding high pulse currents during the distraction period of DO.

3 Results

3.1 Battery Selection. Energy and power data for a full DO process of 15 mm of distraction was summed per time segment to generate aggregate system parameters for battery selection. These values for capacity (72.17 mA h), energy (0.266 W h), specific energy (53.2 W h/kg), energy density (133 W h/l), specific power (47.15 W/kg), and power density (117.88 W/l) are listed in Table 5. As the device requires relatively high current of up to 70 mA, high power electrochemical systems were expected as possible candidates, including most of the lithium-based chemistry with various form factors. Based on the commercial battery database, a polymer lithium-ion (Li-ion) rechargeable battery (UBC322030, Ultralife Batteries, Newark, NY) was found to satisfy the required high current discharge within the minimum size and recommended by the battery selection algorithm (Table 6).

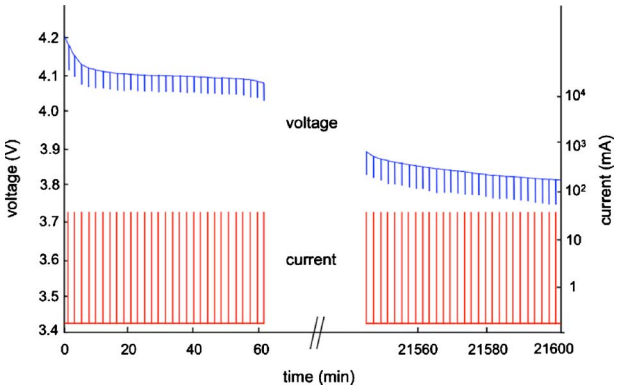

Fig. 3 Pulsed current and voltage profile of the selected UBC322030 battery for 15 days distraction process. The required pulse current was 60 mA for 100 ms every 2.5 min with a continuous current drain of 150 μA.

3.2 Battery Performance: Pulse Discharge Characteristic. The performance tests followed to confirm the theoretical battery selection. The pulse load profile simulating the actual distraction protocol was used to verify that the polymer Li-ion battery sustained the pulsed current drain for more than 15 days, which was equivalent to up to 15 mm of distraction, supposing that the current drain was regulated as a given control scheme and that the environmental temperature remained at 37°C. The voltage drop after 15 days of pulsed discharge test was 0.46 V under pulsed load, resulting in a 65% capacity use out of the rated 120 mA h capacity (Fig. 3).

3.3 Device Prototype. Based on the mechanical element design, the control circuit design, and the battery selection described in the previous sections, a benchtop prototype was built to satisfy the functional requirements and biological/geometric constraints (Fig. 4).

4 Discussion

4.1 Comparison to the State-of-the-Art. Distraction osteogenesis in the craniomaxillofacial region is possible in the maxilla, the mandible, and the alveolar and cranial complexes. For example, distraction osteogenesis is routinely performed in neonatal infants with Pierre Robin sequence, a congenital anomaly

Table 5 Power and energy requirements for distraction of 15 mm (pulse current for 100 ms during actuation, mass (kg=0.005), and volume (l=0.002))

Mode	Power (mW)	Voltage (V)	Current (mA h)	Capacity (mA h)	Energy (W h)	Specific energy (W h/kg)	Energy density (W h/l)	Specific power (W/kg)	Power density (W/l)
Sleep	0.58	3.7	0.158	56.88	0.209	41.8	104.5	0.0116	0.029
Active	235.69	3.7	63.70	15.29	0.057	11.4	28.5	47.14	117.85
Total	236.27	3.7	Total	72.17	0.266	53.2	133	47.15	117.88

Table 6 Selected battery specification: UBC322030 polymer Li-ion battery

Battery type	Part number	Mass (kg)	Volume (l)	Height (mm)	Length (mm)	Width (mm)	Area (cm^2)
Polymer Li-ion	UBC322030	0.003	0.00267	3.7	31.0	21.0	16.87

Capacity (mA h)	Maximum discharge current (mA)	Minimum/maximum voltage (V)	Minimum/maximum temperature (°C)	Specific energy (W h/kg)	Energy density (W h/l)	Specific power (W/kg)	Power density (W/l)
120	240	3/4.2	−20/60	146.0	230.0	240.0	269.7

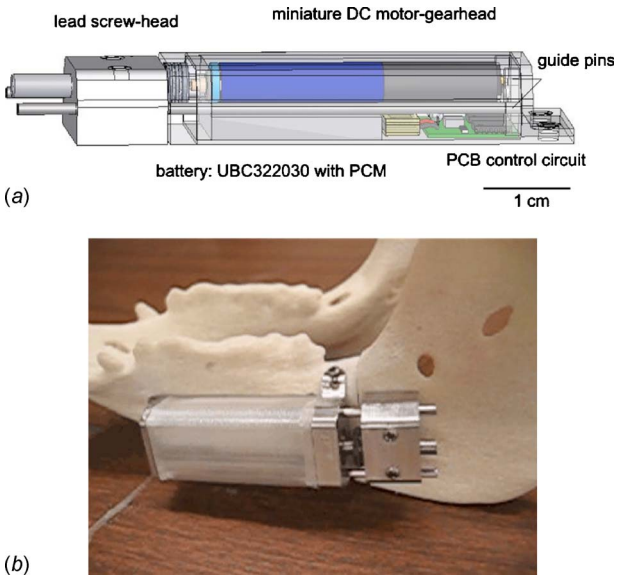

Fig. 4 Prototype device design and fabrication: (*a*) computer-aided design and (*b*) prototype device on a mandible model

that leaves the infant with micrognathia, which may be severe enough to cause airway compromise. To accomplish this, there are several devices currently on the market. This includes the popular Zurich pediatric ramus cloverleaf design (KLS-Martin, Tuttlingen, Germany) device. This device and several other similar devices are small and require surgical implantation. The bulk of the device comes from the activator arm, which, in terms of actual force application, is redundant and is only needed for parental distractor activation. The ability to eliminate this redundant material would be a significant breakthrough for the patient and family in terms of surgical morbidity, scarring, and disfigurement. The above mentioned Zurich device is 15 mm in length, not including the activator arm. This device, despite its small size, is sufficient enough to generate the forces necessary to distract the pediatric mandible at 1 mm/day, which is approximately 4.2 N cm of torque or 35.6 N [18].

Our device, when including the activator, is similar or even smaller in dimensions to current on-the-market devices and is capable of producing the required forces for pediatric mandibular distraction osteogenesis in a continuous distraction as opposed to the present technology of intermittent distraction. Furthermore, the device size can be significantly reduced for commercial manufacturing, especially with a custom actuator, an embedded circuit chip, and a better casing. Because the prototype device was fabricated all in house, there were some limitations in selecting materials and in fabricating complicated and miniature parts. However, we believe that our prototype device served well for its role of demonstrating the design concept and functionality for the continuous automatic distraction osteogenesis device. We are developing a continuous distraction device as opposed to all the other devices on the market that are intermittent. The critical limitation of intermittent force application with both internal and external procedures motivates the development of new devices for distraction osteogenesis of both the craniofacial complex and orthopedic long bones.

4.2 Battery Selection. The battery selection from the commercially available battery database resulted in a polymer Li-ion battery, as shown in Table 6, which provides the performance characteristics of Li-ion batteries including high specific energy and high energy density within a thin, high aspect-ratio form factor. A thin film-type form factor addresses the main advantages of the battery by providing minimal thickness and favorable geometry for high power generation. As the polymer Li-ion cell employs a gel-type electrolyte absorbed into a thin polymeric binder along with active materials as $C/LiMn_2O_4$, it does not require rigid packaging for liquid electrolytes, and thus, it can provide higher energy and power density within smaller thickness compared with those of typical Li-ion cells in metallic cases. Also, its high surface-volume ratio is favorable to provide improved pulse discharge characteristics required for the actuation of distraction device.

4.3 Safety Issues. The use of Li-ion battery may impose significant safety issues. Lithium and Li-ion batteries have been used in various implantable devices, as summarized in Table 2, including an artificial heart. In these devices, the safety of the Li-ion battery regarding its heat generation has been demonstrated. A study by Okamoto et al. addressed the safety issue specifically related to the same type of polymer Li-ion battery as we used for our device [25]. The heat generation from the battery in their study has shown to be dependent upon the state-of-charge (SOC), and a SOC of 50–100% results in only a slight temperature rise due to small chemical loss. Small chemical loss leads to the suppression of damage in the chemical structure of the battery. Cycled batteries within 50% SOC showed minimal or almost no temperature rise. In other words, as long as the implanted battery is cycled within a controlled voltage range, it is safe of excessive heat or even explosion. In our design, the battery needs to be discharged only up to 50% of SOC. Moreover, the distraction osteogenesis operation requires the battery to be discharged only once without the multiple charging-discharging processes, which make the battery and device extremely safe.

Another important safety issue of the implantable medical device is its biocompatibility. The critical temperature of tissue damage was given in a study by Suzuki et al. and was set as one of the design criteria [23]. According to the study, any temperature higher than 37.8 °C may lead to moderate temperature tissue damage. To prevent the excessive heat from the device, we used heat-sealing polymeric materials, surrounding the actuator and the battery. The prototype device was used to demonstrate that the device design is safe from any heat generation. We observed no heat or temperature rise from the exterior of the prototype device. Furthermore, the current device design involves various materials covering different components including motor-gearhead, bearing, lead screw, and battery. All the components were built in a biocompatible case due to any possible steel/bronze loss. This also protects the battery and the control circuitry from humid environment in the body.

5 Conclusion/Future Work

A continuous automatic distraction device for mandibular DO was designed and demonstrated using a battery powered micromotor actuator with a control circuit; the key conclusions from the device design are as follows.

(1) A polymer Li-ion battery, UBC322030, has been selected from the commercially available batteries through a MATLAB algorithm and tested under a pulsed discharge profile, representing the equivalent clinical distraction protocol.
(2) The test results verified the pulse capacity, the performance characteristics of the polymer Li-ion battery were satisfactory to operate our device, and the POWER algorithm was confirmed as an effective tool of selecting a battery for an implantable medical device.
(3) The benchtop prototype of the device can be fabricated for animal studies using miniature pig models and implanted for human clinical application.
(4) Custom component design and fabrication including a micromotor and batteries can realize further minimization of the device, which might be required for the cases of younger patients (<2 years) or infants.

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