Optimization of Hardware and Software Design for New Artificial Anal Sphincter Low Power System

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Abstract. Most artificial anal sphincters have a large power consumption, which is not suitable to long-term implantation of the system in the human body to help patients with anal incontinence recover. In this article, in order to reduce the system power consumption, both hardware and software optimization design have been considered. For hardware, both motor drive module and sensor module have been optimized for long-term implantation of the system in the human body. On the other side, for software, a low-power system is designed and optimized. According to the relationship between the sampling period and power consumption, the best sampling period is determined. Due to the huge difference in power consumption between the working mode and standby mode of the communication module, a new wake-up mechanism is designed for the communication module, so that the power consumption is further reduced. In the vivo experiments, the results show that the standby time can be up to 13 days when using the optimization system, which is extended significantly compared with the previous artificial anal sphincter.

1. Introduction

Fecal Incontinence (FI) is a symptom of bowel dysfunction, which refers to the inability of the patient to store intestinal contents and cause frequent bowel movements [1, 2]. Fecal incontinence has various causes. Although it does not directly threaten the life of patients, it seriously affects the quality of life and physical and mental health of patients [3]. Existing fecal incontinence therapies, such as ostomy, have limitations and poor treatment effects. Artificial anal sphincter, as an implantable medical solution for the treatment of fecal incontinence, has broad prospects and has the potential to completely solve the problem of fecal incontinence. It has become a research hotspot in the field of FI treatment [4].

The earliest artificial anal sphincter is Artificial Bowel Sphincter (ABS), which is inspired by urethral sphincter. It is manually controlled by a water pump and does not integrate any sensors and circuits [5, 6]. French scholars have developed Magnetic Anal Sphincter (MAS), which is composed of several magnetic beads connected in series. It uses magnetic force to control bowel movements. After the intestinal contents reach a certain volume and mass, beads are stretched to complete defecation. There is no active control process. In addition, like ABS, it is without any sensors and circuits [7]. The German Artificial Sphincter (GAS) developed by German researchers uses a bidirectional piezoelectric micro pump to transport liquid between the integrated liquid storage bag and sleeve to...
realize the expansion and contraction of the sleeve to control stool and defecation. Lithium batteries are used in the GAS system for power supply, and a built-in pressure sensor can monitor the liquid pressure in the sleeve. However, its response time is up to several minutes. The overall power consumption is large, regardless of the power consumption generated by sensors and communications. When it operates three times a day under the best working conditions, the battery can only support 4 days. In addition, the function of feeling awareness has not been established [8]. Puborectalis-like Artificial Anal Sphincter (PAAS) uses a flexible toroidal pressure sensor to detect the pressure of the intestinal wall. Pressure information is sent periodically to the external control terminal through the communication module. When the pressure is detected to exceed the threshold, the external control terminal will send out a defecation alarm to remind the patient to defecate. But the overall power consumption of PAAS is relatively large. It can only be standby for a few days on a single charge [9].

To solve the power consumption issues above, optimization of hardware and software design of an PAAS is proposed. Section 2 is the PAAS system review. Section 3 provides details about the analysis of hardware system design, which is mainly include optimization of motor driver module and sensor module, and the research of optimization of software, which focuses on its low-power system analysis. Accordingly, in vitro experiments are conducted in section 4 to prove the reliability and stability of the optimization design. Finally, in section 5 conclusions are presented.

2. PAAS- system overview
Puborectalis-like Artificial Anal Sphincter system, as is shown in Fig. 1, includes wireless power transfer system and control unit. Wireless power transfer system is the power supply for the PAAS system. The control unit is implanted in body, of which the clamping mechanism could do actions of clamping and relaxing rectum for controlling defaecation. In addition, pressure sensors are imbedded in control unit to remodel rectal perception.

![Figure 1. The structure of PAAS system.](image)

3. Optimization of hardware and software design
At present, most artificial anal sphincter has a large power consumption, which is not conducive to long-term implantation of the system in the human body to help patients with anal incontinence recover. Therefore, it is necessary to reduce the system power consumption by optimization of hardware and software design.

3.1. Analysis of hardware system design
**Optimization of motor driver module**

DRV8837 motor driver is used to make motor rotate in a forward or reverse direction, which drives artificial anal sphincter to realize excretion and continence. The function principle of motor driver module is shown in the Fig.2.

When receiving the motor rotation command sent by the host computer, MCU will change the configuration word of corresponding pins on DRV8837. The motor realizes forward and reverse rotation by the change of high and low potential on pins connected with the chip and the motor. During the clamping process, the working current of the motor can be increased from 50 mA to 1 A with the increase of the clamping torque. In order to prevent excessive current from damaging the
control circuit, the current intensity should be detected in real time. In particular, based on the series characteristics of DRV8837 chip and power supply chip, a 0.1 Ω sampling resistor is added to sample the current by detecting the voltage drop generated by the resistor. Due to the small resistance, the collected voltage signal is weak, so it is necessary to use an operational amplifier. After the signal is amplified, it is transmitted to the corresponding current detection port of the MCU and compared with the threshold. MCU will cut off the power supply of the DRV8837 once the current exceeds the threshold.

The motor current has a large variation range. When choosing a voltage regulator, in addition to considering the package size, it is also necessary to meet the maximum actual working current of the motor and ensure that the heat generation cannot be too much. In previous artificial anal sphincter system, LT1763-3.3 was used [13]. Although it is small in size and can accurately output 3.3 V voltage, its maximum operating current of 500 mA and extreme heat generation under high load cannot meet system requirements. Therefore, in new system, NCP708 is adopted as voltage regulator. The chip not only has a maximum operating current of 1.5 A, but also has a small size and simple peripheral circuit, which is deemed suitable for motor driver module.

**Optimization of sensor module**

In order to rebuild rectal perception and safe continence function, multiple sensors have been used in artificial anal sphincter system. They are mainly responsible to monitor various parameters, such as temperature, position and pressure. The signals collected by the pressure sensors and temperature sensors are week, which need to be amplified before being processed by MCU. While to signals produced by hall effect sensors, they can be processed by MCU without amplification. The sensor module is shown in Fig. 3.

![Figure.3 Block diagram of sensor module](image)

C29 pressure sensor is adopted, which detects dot pressure. In order to monitor the pressure on intestinal surface accurately, C29 is redeveloped to detect area pressure. When the force works on the sensor, the mechanical deformation signals are transformed to voltage signals, which is amplified by LTC2053 before output to MCU. There are five pressure sensors in system. In previous artificial anal sphincter (AAS), five operational amplifiers were used corresponding to five pressure sensors [2], which causes a great waste of circuit board area, especially to limited space in the device. In new system, analog multiplexer is adopted with one operational amplifier. In particular, different sensors can be selected by switch channels, then input to MCU through the same operational amplifier.

Hall effect sensor A1171 is used to detect position of middle ring. Magnet is placed on the middle ring, swinging with the middle ring. Hall element can generate potential difference by inducing the intensity of the magnetic field. Then the position of middle ring can be controlled in a safe range.

High precision thermistor is adopted as the temperature sensor. The voltage drop on the resistor can reflect the temperature change of the charging circuit. The tissues in the body are very sensitive to temperature, but the heat generation is inevitable during charging. A temperature sensor is added to the Puborectalis-like artificial anal sphincter system to monitor the temperature. When the sampling temperature exceeds the threshold, the charging circuit is cut off to ensure the biological safety of the system.
3.2. Optimization of software low-power system

In PAAS system, a rechargeable battery with 350mAh and 3.8V is used. The main power consumption components and power consumption of internal subsystem is listed in Table 2-1. It is assumed that the patient poops twice a day after the implantation of the PAAS subsystem. The working time of the system is about 13 hours before the low-power software is optimized. What can be seen in Table 1 is that wireless communication module and sensor module account for about 98.5% of the total power consumption of the system. It can be judged that reducing the power consumption of wireless communication module and sensor module plays a key role in extending the overall working time of the system.

For power consumption reduction, it is a useful way to reduce the working hours of wireless communication module and sensor module. However, unreasonable reduction of working hours will lead to the following contradictions:

a) The reduction in the working hours of the communication module affects the real-time interaction between the internal and external subsystems, which is inconvenient for the user to operate.

Table 1. Main power consumption components and power consumption of internal subsystem

| Test Hours | Items                  | Currents | Power Consumption | Work Hours | Proportion of Power Consumption |
|------------|------------------------|----------|-------------------|------------|-------------------------------|
| 13 hours   | Motor                  | 130 mA   | 429 mWh           | 30 s       | 0.3%                          |
|            | Microcontroller        | 200 μA   | 0.66 mWh          | 13 hours   | 0.8%                          |
|            | Wireless Communication | 17 mA    | 56.1 mWh          | 13 hours   | 67.0%                         |
|            | Pressure Sensor        | 8 mA     | 26.4 mWh          | 13 hours   | 31.5%                         |
|            | Others                 | 100 μA   | 0.33 mWh          | 13 hours   | 0.4%                          |

b) Too low pressure sensor sampling frequency affects the accuracy of pressure monitoring of intestinal excrement.

Then, to solve the problems above, different solutions are adopted.

In sensor module, in order to reduce frequency reasonably to control power consumption, it is necessary to study the relationship between sampling frequency and pressure monitoring accuracy of intestinal excrement. A PPC4 pressure calibrator is used in the following experiment. PAAS systems with six different sampling frequencies are placed in the pressure calibrator. First, adjust the pressure of the pressure tank from 100kPa to 140kPa with an interval of 1kPa every 5 seconds. then reduce the pressure from 140kPa to 100kPa with an interval of -1kPa every 5 seconds. The pressure change is used as the original curve. Then the pressure monitoring accuracy at different sampling frequencies is obtained by comparing the original data with the pressure data sampled by the 6 groups of sensor systems.

The experimental results are shown in Table 2. It can be seen that energy consumption continues to increase as the sample frequency increases. And when the frequency is greater than 4 times/min, the accuracy has reached 99.99%. Obviously, too high frequent does not greatly improve the accuracy of the pressure monitoring, but increases the system power consumption. According to the physiological characteristics of human being, rectal peristalsis is generally slow, so the rate of content change is also slower. A complete defecation and continence cycle may be as long as several hours, and the sampling time of sensor is about 2ms/time, which is much shorter. In fact, a large number of samples are useless data, but power consumption. Therefore, based on the experimental results, 4 times/min is a reasonable sampling frequency. In order to make the sampling more accurate, each sampling contains 10 samples, that is, each sampling takes about 20ms, and the final output data is the average of 10 samples. The energy consumption is improved from 26.4mWh to 3.9mWh, which is significantly reduced after optimizing the sampling frequency of the sensor.
Table 2. Accuracy and power consumption under different package size per minute

| Frequency (times/min) | Power Consumption (mWh) | Accuracy (%) (Ratio of area) |
|----------------------|--------------------------|-----------------------------|
| 1                    | 0.8                      | 99.76                       |
| 2                    | 1.9                      | 99.93                       |
| 3                    | 2.8                      | 99.96                       |
| 4                    | 3.9                      | 99.99                       |
| 5                    | 4.8                      | 99.99                       |
| 6                    | 6.1                      | 99.99                       |

In communication module, in order to ensure the daily operation of the PAAS system by patients, while reducing system power consumption, the communication module should possess the ability to response to the command sent by the handset at any time, and go into standby mode in the rest of the time. The internal wireless communication chip is used as the active inquiry terminal. When a handset sends a command, it is not responded by the internal subsystem immediately, instead, the command is stored in the FIFO register of the external wireless communication chip. And flag bit is set ‘1’. At the cycle of every 15 s, the internal communication chip first uploads the sample data collected by sensors within 15 s, and at the same time queries the FIFO register flag bit. If flag bit is ‘1’, the communication module exits standby mode and receives the command from handset. If flag bit is ‘0’, the communication module continues to keep standby mode. Since the response time of the SI4431 chip is milliseconds, and the normal defecation time is about 3 to 7 minutes [15], the waiting time of 15 s will not affect the patient’s defecation. Working diagram of AAS software after optimization is presented in Fig. 4. After the optimized design, the current consumption of the communication chip in the low-power cycle is only 100μA, which is much less than the 17mA in previous system.

![Figure 4 Working diagram of PAAS software after optimization](image)

Figure 4 Working diagram of PAAS software after optimization

![Figure 5 Positions of charging module in in-vivo experiments.](image)

Figure 5 Positions of charging module in in-vivo experiments.
4. In vivo experiments
In April 2018 and April 2019, two in vivo experiments were conducted on Pa Ma piglets, shown in Fig. 5. In each experiment, two piglets, which were both about 4 months old, with an average weight of 26.2kg, were picked up to implant the artificial anal sphincter. Surgeries were conducted by physicians at the Shanghai No. 6 People’s Hospital. All artificial anal sphincters were disinfected before implantation. Procedures involving animals were conducted in accordance with the ‘Guiding Opinions on Treating Experimental Animals’ issued by the Ministry of Science and Technology in 2006. The lithium batteries of the same model were used in four sets of in vivo experiments. The difference in battery capacity is less than 5mAh. It should be noticed that the optimized system for power consumption has been applied in experiments in 2019, compared with experiments in 2018.

In each experiment, the battery was fully charged through transcutaneous energy transmission when the institution ran out of power for the first time after implantation. Then it entered the power consumption experimental cycle. The device was set to operate twice a day. Each time the working mode was set as 15 minutes, and the rest of the time entered the standby mode to collect the pressure information and send them to the external control terminal. The one cycle of power consumption experiment ends when the power of the institution runs out, and the duration is recorded.

Results are listed in Table 3. After implantation, the working duration of the system in the body on a single charge has been extended from about 12 hours to about 11 days, and the improvement is obvious.

| Table 3. Duration of two PAASs with low power costing data collection system |
|---------------------------------------------------------------|
| Number of Test | PAAS Generation 1 | PAAS Generation 2 |
| Maximum Work Time (days) | 0.5 | 13 |
| Minimum Work Time (days) | 0.4 | 9 |
| Average Work Time (days) | 0.46 | 10.9 |

The low-power consumption design makes the PAAS internal subsystem work longer after a single charge. Reduction of charging frequency makes it more friendly and comfortable for user experience. In addition, the battery life can be extended, which in turn allows the system to work longer.

5. Conclusions
In this article, the power consumption of artificial anal sphincter is analyzed in modules. In order to reduce the system power consumption, both hardware and software optimization design have been considered. For hardware, both motor drive module and sensor module have been optimized for long-term implantation of the system in the human body. On the other side, for software, a low-power system is designed and optimized. According to the relationship between the sampling period and power consumption, the best sampling period is determined. Due to the huge difference in power consumption between the working mode and standby mode of the communication module, a new wake-up mechanism is designed for the communication module, so that the power consumption is further reduced. In the vivo experiments, the results show that the standby time can be up to 13 days when using the optimization system, which is extended significantly compared with the previous artificial anal sphincter. The hardware and software optimization design makes the PAAS internal subsystem work longer after a single charge, and reduces the frequency of internal subsystem charging, which enhances the user experience.

Funding
This research was funded by Shanghai Science and Technology Support Project (No.19441910600, No.19441913800) and Science and Technology Projects in Shanghai Minhang District (2019MHC053).
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