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A MINIATURE-IMPLANTABLE RF-WIRELESS ACTIVE GLAUCOMA INTRAOCULAR PRESSURE MONITOR

Dr.R.Satish Kumar [1], Paranika. S[2], Vanitha Sri.V[3], Vennila.V[4], Vinothini.K[5]
Principal[1], UG Scholar[2],[3],[4],[5],
Department of Medical Electronics Engineering,
Sengunthar College of Engineering, Tiruchengode. Tamil Nadu, INDIA
[1]harsiga@gmail.com, [2]shajana220299@gmail.com,
[3]vanithasrivadivel@gmail.com,[4]vennilahoney08@gmail.com, [5]vinothinikumar9481999@gmail.com

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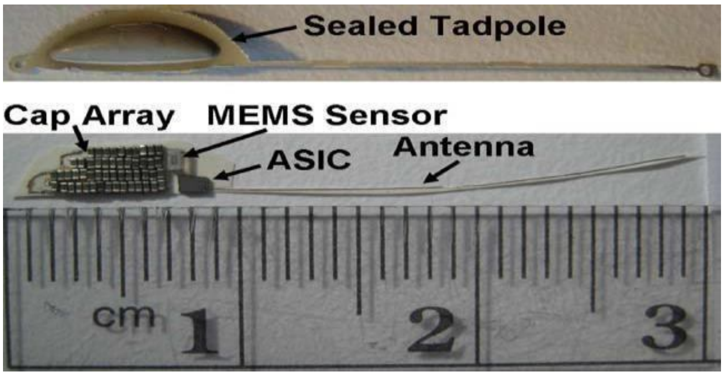
Abstract: Glaucoma is a detrimental disease that causes blindness in millions of people worldwide. There are numerous treatments to slow the condition but none are totally effective and all have significant side effects. Currently, a continuous monitoring device is not available, but its development may open up new avenues for treatment. This work focuses on the design and fabrication of an active glaucoma intraocular pressure (IOP) monitor that is fully wireless and implantable. Major benefits of an active IOP monitoring device include the potential to operate independently from an external device for extended periods of time and the possibility of developing a closed-loop monitoring and treatment system. The fully wireless operation is based off using gigahertz-frequency electromagnetic wave propagation, which allows for an orientation independent transfer of power and data over reasonable distances. Our system is comprised of a micro electromechanical systems (MEMS)pressure sensor, a capacitive power storage array, an application-specific integrated circuit designed on the Texas Instruments(TI) 130 nm process, and a monopole antenna all assembled into a biocompatible liquid-crystal polymer-based tadpole-shaped package.

INTRODUCTION

Glaucoma stems from a buildup of intraocular pressure (IOP) in the anterior chamber of the eye which mechanically constricts and damages the optic nerve, eventually leading to irreversible blindness. Primary open angle glaucoma is the most common type and results from occlusion of the drainage pathway presented by the trabecular meshwork and Schlemm’s Canal. The trabecular meshwork is an area of tissue in the eye responsible for draining aqueous humor from the anterior chamber, which is between the iris and the cornea. The aqueous humor then passes through a set of tubes known as Schlemm’s canal where it then flows into the circulatory system. Glaucoma is predicted to affect about60.5 million people by 2010, of which 4.5 million will develop bilateral blindness [1]. Oftentimes in cases of open angle glaucoma, the individual has no symptoms or warning signs, and the disease gradually progresses leading to eventual blindness. Current clinical devices do not provide 24-h monitoring and may not be sufficient for at-risk patients due to the fact that IOP varies significantly throughout the day and can be substantially greater at sometimes such as during intense activity or while sleeping [2], [3]. This paper focuses on the development of an implantable device, shown in Fig. 1, which can provide continuous measurements of the internal pressure of an eye. This data can be used to monitor the progression of the disease in glaucomatous patients and can hopefully help prolong vision and even prevent blindness. There are numerous continuous glaucoma IOP monitoring devices in the research-and- development phase. A popular technique is integration of a strain gauge pressure sensor into a soft contact lens. The Triggerfish® developed by Sensimed AG [4] has developed a method to make this approach completely wireless.



The approach faces problems due to the fact that the nature and positioning of a contact lens causes the measurements to suffer from considerable noise and variability due to eye movement, blinking, and external environmental conditions, such as moisture, that could alter the form of the lens [5]–[7]. Internal glaucoma pressure monitors do not face that same problems and numerous works have described implantable passive LC resonant-based systems [8]–[15], which promote a device that is simple, robust, and somewhat small (maximum of 3–6 mm in its widest dimension). The main drawbacks of these passive devices are very limited functionality, only on-demand measurements, and the constant requirement of a nearby external data acquisition unit.

Active implantable IOP monitors have also been explored and two of the leading active devices in the area are presented in [16] and [17]. These devices, which use an implantable lens approach, are relatively large, use inductive power coupling which limits the range and requires perfect alignment with an external powering coil, and still constantly requires a nearby external device.

In this paper, we describe in detail the design of an active wireless implantable IOP monitoring system, introduced in [18], which consists of an application-specific integrated circuit (ASIC), micro electromechanical systems (MEMS) sensor, antenna, and capacitive powering array. The MEMS sensor is used to convert pressures into capacitance and is fed into the ASIC for data processing and modulation onto a high-frequency carrier for wireless transmission. The assembled device and liquid-crystal polymer (LCP)-based package is shown in Fig. 1 and is roughly the shape of a tadpole to facilitate trochanter-based surgical implantation in the anterior chamber of the eye.

SYSTEM DESIGN

Our glaucoma IOP monitoring device is a fully wireless active low-power measurement system. The primary advantages of this active system include the potential for a vast increase in functionality and the ability to operate for extended periods of time without a constant nearby external device which powers and/or extracts data. The ASIC is designed on the Texas Instruments (TI) 130 nm technology and consists of a sensor interface, voltage regulators and references, radio-frequency (RF) rectifier for remote powering, and wireless transmitter.

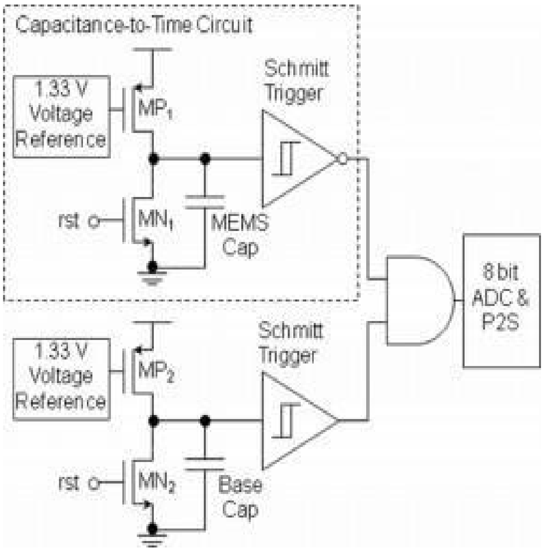


Fig: simplified schematic of capacitance-to-time circuit

CAPACITANCE-TO-TIME CONVERSION

To support the wireless features, a monopole antenna is designed and integrated onto a Rogers Corporation LCP substrate. To allow for independent operation, a capacitor array that fits within the size constraints of our miniature package is used to provide power storage and eliminate the need for a continuous nearby external device. An ultra-low-power measurement technique is used in the sensor interface and utilizes a nano amp current to charge the MEMS capacitor converting capacitance variations to time changes. The capacitance-to-time circuit is shown in Fig. 2where the top plate of the MEMS sensor is connected to the “*cap*” pin and a PMOS current source supplies current to that pin. When the node voltage reaches the threshold of the Schmitt trigger, the output switches logic levels from high to low. The time between when the current source begins charging up the top plate and when it reaches the threshold is directly proportional to the capacitance of the sensor. This block is reset by setting the “*rst*” pin to a logic level “high” causing the NMOS transistor to drain out all of the current from the Cap node.

VOLTAGE REGULATOR AND REFERENCES

The voltage regulator is supplied by the power capacitor array which can vary from 4 V down to 0 V. To maximize the usable charge, a common PMOS with operational amplifier feedback topology is used, which allows for low dropout voltage operation [19], [20]. An NMOS-based operational amplifier design with an NMOS current source is used in order to guarantee a constant overdrive voltage over the range of the supply. The regulator requires a reference that is stable across the voltage variation of the capacitor powering array and, thus, a modified form of the supply- independent reference circuit from [21] is used. Diode-connected transistors are used in both branches of this reference topology to achieve the desired voltage while minimizing area and reducing power consumption. To minimize the overall average power consumption of the system, a picowatt timer, similar to that presented in [22], designed to track 5-min intervals, can be used to gate the charge supply to the regulator.

DIGITAL CONVERSION

Digitization is required for noise immunity and to allow for storage into on-chip memory. Digital conversion is done using an 8-b ripple carry counter with an asynchronous reset function that is designed to measure the corresponding width of the pulse. The counter is controlled by a clock, generated using a current-starved ring-oscillator topology, whose frequency is determined based on the pulse widths, specifications of the MEMS sensor, desired pressure range of 50 mmHg, and required sensitivity of at least 0.5 mmHg. The pulse controls the clocking of the binary counter, and the falling edge of the pulse is used to stop and reset the counter and prepare it for the next conversion. After the count sequence, the value of the counter is fed into a parallel-to-serial converter, designed using a standard 12-b shift register topology, to serially stream out the digital data either directly to the wireless transmitter or into on- chip memory. The regulator requires a reference that is stable across the voltage variation of the capacitor powering array and, thus, a modified form of the supply- independent reference circuit from [21] is used.

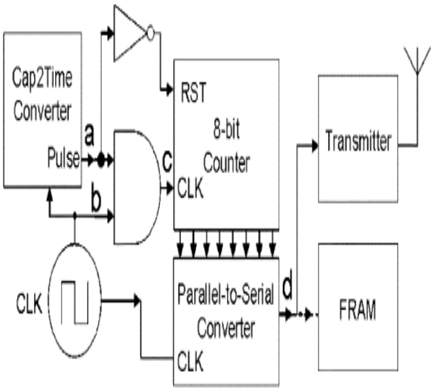


Fig: Block diagram of the digital conversion architecture

CAPACITIVE POWER- STORAGE ARRAY

An ultra-low-power ASIC design is absolutely crucial in the design of the IOP monitoring system. Current miniature battery technologies are relatively large and would exceed the size constraints. To meet the clinical size requirements, high-dielectric ceramic surface- mount capacitors are used to provide a power storage unit. Miniature 0201 capacitors are used to meet the thickness constraint of 300 m and we chose the largest readily available capacitance of 0.47 F for our corresponding package. The size constraint of our device enables us to integrate 52 of these capacitors and this array has the potential to power the complete system over a 24-h period.

For completely independent operation, on-chip memory is also required to store the pressure data. At the end of every 24-h monitoring period, an external device is brought nearby which wirelessly downloads the data and recharges the capacitor array. The LCP is available with a layer of copper clad on each side allowing for the etching of traces using a mask photolithography process and a ammonium per sulfate etchant. Long-term biocompatibility and stability tests on LCP are presented in where inflammation and other complications are examined over a 3-month period. Accelerated soak tests on LCP are also presented in [30] to evaluate long-term reliability through at temperatures from 37 C up to 75 C and show no degradation and good long-term biocompatibility.

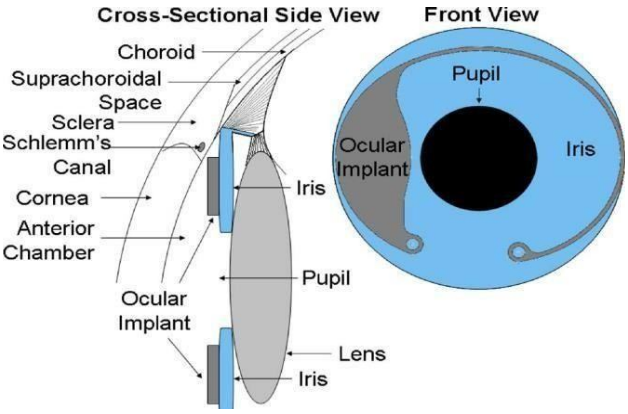


Fig: Cross-sectional and front view of the eye showing the target implant location.

MEASUREMENTS AND RESULTS

The IOP monitoring application specific integrated circuit (ASIC), shown is fabricated through the Texas Instruments (TI) 130-nm CMOS process.

WIRELESS TELEMETRY AND POWERING

The fabricated 2.4-GHz transmitter consumes 812 A from a 1.5-V regulated supply and outputs 45 dBm. The on-chip fully- symmetric differential inductor with a patterned ground shield has a measured of 10.36 at 2.4 GHz. The data rate is inversely proportional to the system average power consumption when using a bursty transmission technique since faster wireless telemetry reduces the transmitter on-time for a given amount of simulated to be about 150 ns, limits the maximum date rate. Through empirical testing, an optimal point in free-space is found at a data rate of 8 Mb/s when considering maximizing the data rate and minimizing the bit-error rate (BER). It is important to note that even though the actual measured values of BER depend on distance, the trend of BER versus data-rate is independent of distance. At 8 Mb/s and a free- space distance of 50 cm, the transceiver link has a sensitivity of 80 dBm and a measured BER of 7.5, when tested over 1 b. In the current implementation, a standard communication protocol is not used and the receiver simply listens to data and takes it as is. As a result, errors are likely in a non controlled environment, and the next revision of this system utilizes a standard communication protocol and incorporates error detection and correction schemes.

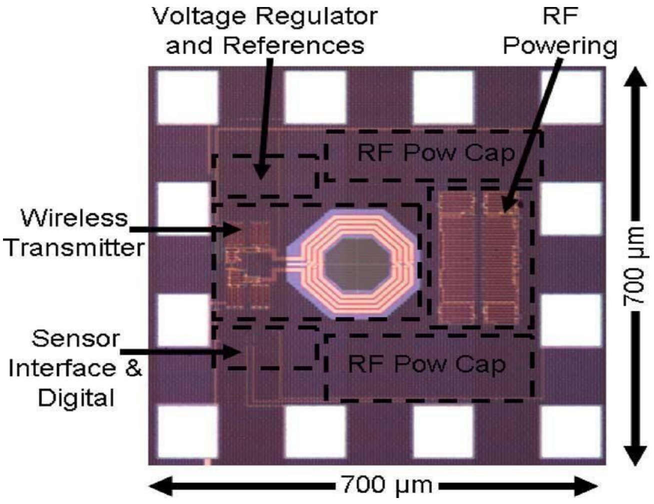


Fig: Optical microscope picture of ASIC.

PRESSURE MEASUREMENT

For the initial testing of the capacitance-to- time measurement block, variable capacitors are used to set the base and sensor capacitances. The capacitances are set using an automated stepper motor integrated with a custom-made plastic screwdriver to precisely set the values. The capacitances are verified using an Agilent The sensor interface is then integrated with the MEMS capacitor, base capacitance, and tested with the wireless enabled. The base capacitance is 5.3 pF, the average sensitivity is 6.64 fF/mmHg (with a maximum variation of about 9.7 fF/mmHg). For testing and validation, the output of the capacitance-to- time circuit is fed directly into the wireless transmitter. An external receiver is used to receive the wireless signal and perform demodulation to recover the data. Empirical tests involved enclosing the fully functional wireless prototypes inside a custom-built pressure chamber while the wireless power source and data receiver are positioned externally.

CONCLUSION

The system presented in this paper provides an active IOP monitoring system that operates over a 24-h period and records pressure data every 5 min. A MEMS sensor captures the pressure data and a custom- designed ASIC processes and digitizes these measurements. These data can either be transmitted out directly to an external device or stored into on- chip memory (FeRAM). If on-chip memory storage is utilized for independent operation, at the end of the day, an external device is brought nearby to download the pressure data and recharge the implant. The implant has onboard power storage as well as wireless recharging and telemetry capabilities. This work describes the design and assembly of a monitoring device that can detect elevated levels of IOP for the diagnosis and treatment of glaucoma.

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