Wireless Micromanometer System for Chronic Bladder Pressure Monitoring

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***Abstract*— This paper describes a wireless system to monitor urinary bladder pressure comprising an implantable device with an external receiver and wireless battery charger. The device is intended to be implanted within the bladder wall, sealed behind the urothelial lining. This location is protected from the urine stream, thus avoiding mineral encrustation and stone formation, and is suitable to measure intravesical pressure in chronic applications. The implant is dimensionally designed to gain access to the bladder using conventional urological tools, i.e. cystoscope. The active circuit implant features a custom application-specific integrated circuit (ASIC), rechargeable battery and wireless telemetry. Inductive charging, novel power management schemes and innovative packaging allow this device to be inserted through the urethra, implanted within the bladder wall, and operate for a lifetime of up to 10 years.**

***Keywords*— implantable biomedical devices, pressure measurement, telemetry, urinary system, wireless sensors.**

I. Introduction

THE proposed wireless system is designed to monitor bladder pressure during chronic applications. The concept (Fig. 1) integrates several cutting edge technologies to create an implantable wireless micromanometer and supporting external equipment, and also suggests a novel location for an implant to measure intravesical pressure. A miniaturized, active device with a creative wireless battery recharging method could be implanted in internal organs for continuous data transmission or intermittent retrieval of stored data. This paper discusses initial application of the device in regard to the urinary bladder, but it is conceivable to extend its utility to other biological systems.

Physiological pressures are measured as an aid to medical diagnosis and monitoring across a wide scope of clinical disciplines, such as those concerned with the cardiovascular, respiratory, gastrointestinal, urological and other systems of the body. Blood pressure is one of the few physiological pressures that can be measured noninvasively, with a sphygmomanometer, but other pressures are typically measured via catheters, either connected to transducers outside the body or more recently by micro-transducers mounted on the tip. However, catheterization tethers the patient to cumbersome external equipment and requires that the catheters be inserted and maintained without infection. While this may be manageable during short term testing, chronic monitoring poses an additional set of obstacles. Unless a patient is bedridden, monitoring is restricted to a snapshot approach in which the physician hopes to capture dysfunction during only a limited window of observation.

II. Application

There are multiple examples from different organ systems of cases in which this snapshot approach is insufficient. Urodynamics utilizes the measurement of bladder pressure and flow to diagnose urinary incontinence, a condition that affects more than half the population above age 60, and, while considered routine, is regarded as not being completely reliable or reproducible [1,2]. It may be difficult to reproduce symptomatic leakage while confined by bed and catheter to the clinical setting. The urethral catheter, inserted to measure bladder pressure, physically obstructs outflow and artificially increases intravesical pressure which renders the results unreliable [3]. As a result, some urologists do not perform urodynamics. Instead they diagnose and treat incontinence based solely on patient reporting of symptoms [4].

Physiological confirmation of patient complaints over a longer time period using an ambulatory system would enable more precise diagnoses and treatments with higher success rates. The *Wireless Implantable Micromanometer* (WIMM) system described in this paper could give patients the freedom to perform their daily activities, in a more comfortable

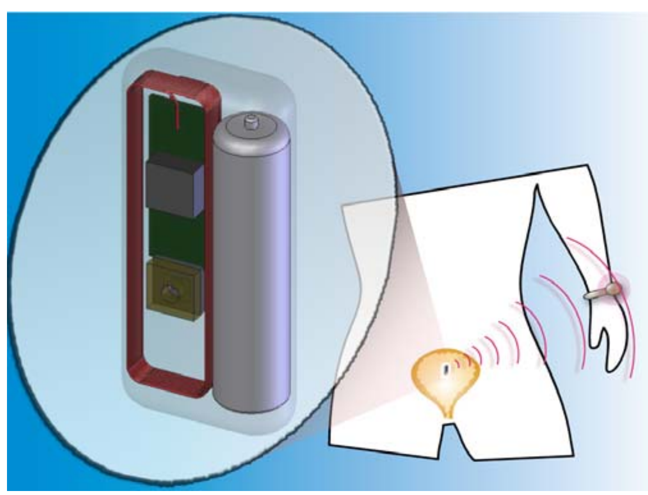

Fig. 1. Artistic conception of the device implanted in the bladder wall, transmitting wireless recordings to an external receiver. The magnified area details the encapsulated components; the telemetry coil wrap around the ASIC and pressure sensor (with pressure port), the battery is outside of the coil, to its side.

environment outside the clinic, while the active and discreet device continuously monitors the users' intravesical pressure. It would be a great advantage to measure pressure using a miniature device that continuously transmits wireless telemetry to an external receiver or stores data in local memory to be extracted at a convenient time. Existing wireless monitors are either passive devices [5] without power in the absence of their external power source or they are active devices with onboard batteries that are too large for our primary application in the bladder [6]. In either case, they can only sense and transmit data for short periods of time, limiting their clinical utility.

Foreign objects chronically located within the lumen of the bladder are subject to mineral encrustation, i.e. stone formation, and also may be expelled during urination. The WIMM sensor is intended to be introduced into the bladder using conventional urological tools, e.g. a cystoscope, and implanted in the bladder wall. A hollow insertion tool, e.g. in Fig. 2, can use its sharp point to pierce the mucosa and create a small pocket in the submucosal area, next to the muscle. An object can be held in this space by the mucosa, which despite its fragile nature has enough mechanical strength to retain that object below. The pressure measured through the urothelium will need to be calibrated to account for attenuation from the tissue [7], but once the bladder heals, the device remains in a secure location that is out of the urine stream, thus reducing the chance of forming stones.

This device would have application for many purposes including diagnostic, monitoring, biofeedback, and as a mechanism to improve control of rehabilitative systems such as those using functional electrical stimulation or neuromodulation. Since no such systems currently exist, this paper conceptualizes a novel medical device that clearly serves an important, yet unmet, clinical need.

The utility of the device conceived here could easily find service in other physiological systems requiring chronic monitoring. Innovative adaptive packaging techniques, tailored to both the local features of the implantation site and the intent of the treatment, is a way of employing the WIMM platform in a variety of applications beyond those urological needs highlighted within this paper.

III. Sensor System Design

The wireless sensor system consists of several sub-systems, as illustrated in Fig. 3, which must be co-designed to meet overall system requirements of size, power consumption, and performance. To accurately measure pressure data from internal organs over the full functional range, the proposed device must be able to measure pressure from 0 to 250 cmH_2O (0 to 184 mmHg) with a resolution of 1 cmH_2O and a precision of 10 cmH_2O [8]. Therefore, we expect to conduct analog-to-digital conversion of pressure data with fewer than 9 bits of resolution. Because internal organs contract and change pressure relatively slowly, a data collection rate of 10 samples per second is sufficient to capture functional activity.

A. System Design

The most critical component of the wireless monitor system is the implantable micromanometer, which must meet stringent size demands consistent with the implantation method. Very

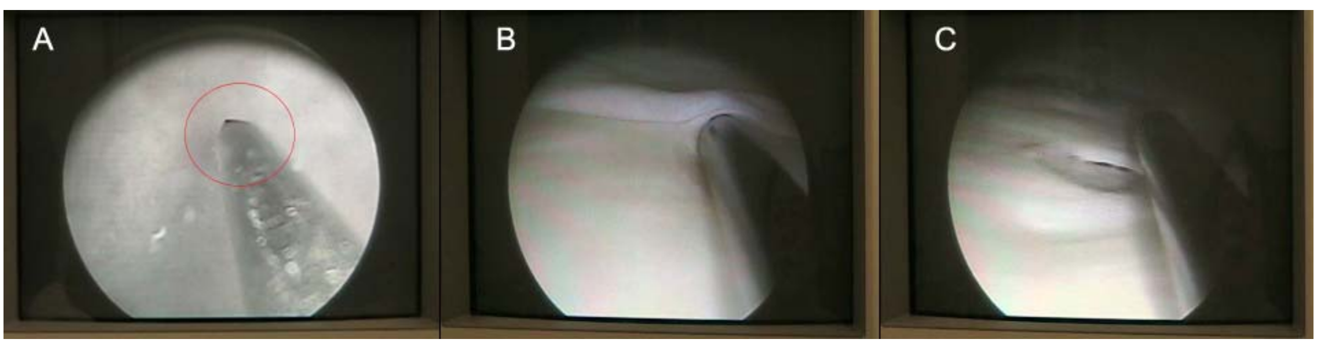

Fig. 2. A view from inside a pig bladder, as seen through a cystoscope. These images were taken during the implantation of a stainless steel pellet and show the cannula tip **(A)**, the cannula penetrating the mucosa **(B)**, and the implantation site immediately after retraction of the cannula **(C)**. The red circle in A indicates the sharpened tip of the cannula as viewed through the cystoscope.

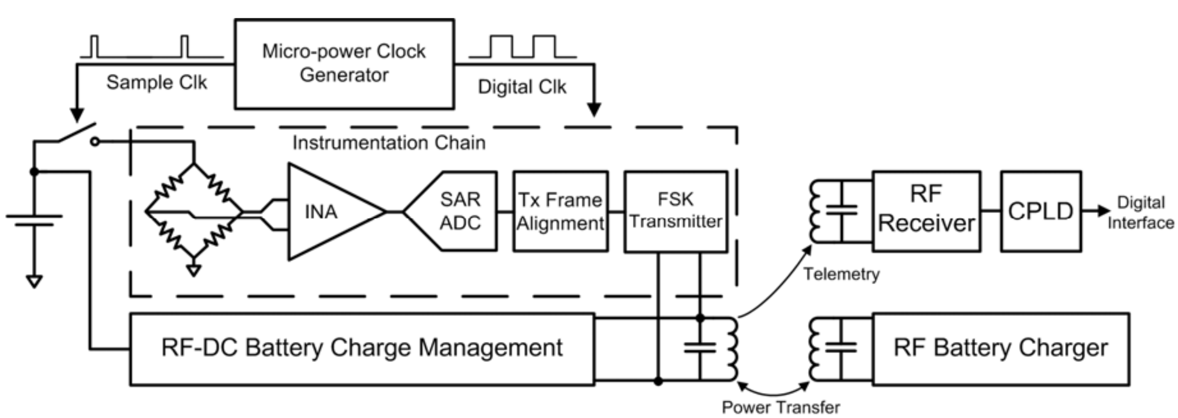

Fig. 3. Block diagram of the wireless micromanometer, showing the implantable device and external support circuits,

strict limitations have been placed on the shape and size in order to facilitate its use with conventional urological equipment; a capsule measuring 7 mm wide by 3 mm thick and 15 mm long, as was illustrated in Fig. 1.

Due to confounding factors such as obesity, the distance between the implant and the external receiver could be as large as 30 cm. It is impractical to power a device implanted that deep in the body solely and continuously through an inductive link. Instead, the micromanometer will be powered by a small rechargeable onboard battery. An inductive antenna on the implant will function as both a transmitting antenna and power link to the external wireless battery charger used during the "recharge" mode, when the wearer is sleeping, e.g.

The two major external components of the wireless sensor system are the RF receiver and the wireless battery charger. The RF receiver will detect and demodulate the weak signal transmitted by the implanted device and send the recovered bit stream to a complex programmable logic device (CPLD) for clock/data recovery, word alignment, and data formatting consistent with a standard microprocessor interface. The receiver is compact enough to allow the wearer unrestrained mobility during normal operation.

The wireless battery charger will use inductive coupling to induce a current in the antenna of the implanted device. This current can be used to recharge the battery. The large distance separating the wireless battery recharger and the implanted device will require a large external antenna and large power dissipation in the recharger, so the battery recharge system will be unwieldy and not portable, but could be built into a mattress and used during periods of sleep.

B. *Implant Design*

In addition to the rechargeable battery, the implantable device will consist of a micromachined (MEMS) pressure sensor, an application-specific integrated circuit (ASIC) and an inductive antenna. The main design requirements for each component are small size and low power consumption.

MEMS Pressure Sensor

An off-the-shelf piezoresistive MEMS pressure sensor has been selected for the initial prototype. More specifically, the SM5102 sensor (from SiMicro) has characteristics which best match the system requirements. In this absolute sensor, the reference chamber is a vacuum, meaning that applied pressures are referenced to zero.

ASIC Architecture

The proposed ASIC architecture is shown on the left side of the block diagram of Fig. 3. To save power, the instrumentation and telemetry chain consisting of the pressure transducer, instrumentation amplifier (INA), successive-approximation analog-to-digital converter (SAR ADC) and frequency-shift-keying (FSK) transmitter will acquire samples only intermittently and will otherwise be shut down. When active, this chain will amplify, digitize, encode, and transmit a single sample from the pressure transducer.

An integrated micro-power clock generator will always run in the background and will control the interval between samples. Because sample rates of 12 Hz are sufficient to measure biomedical pressure, the duty cycle of the instrumentation chain can potentially be near 0.1%. Thus, the average power consumption of the implanted device will be determined by the power consumption of the clock generator plus one one-thousandth of the instrumentation chain power consumption.

IV. POWER MANAGEMENT

The miniature dimensions of the implant preclude the usage of a primary cell for chronic powering. Advanced battery technologies have yielded rechargeable units that can reliably provide acceptable power density in a package small enough to meet the demands of this project. Fig. 4 describes the

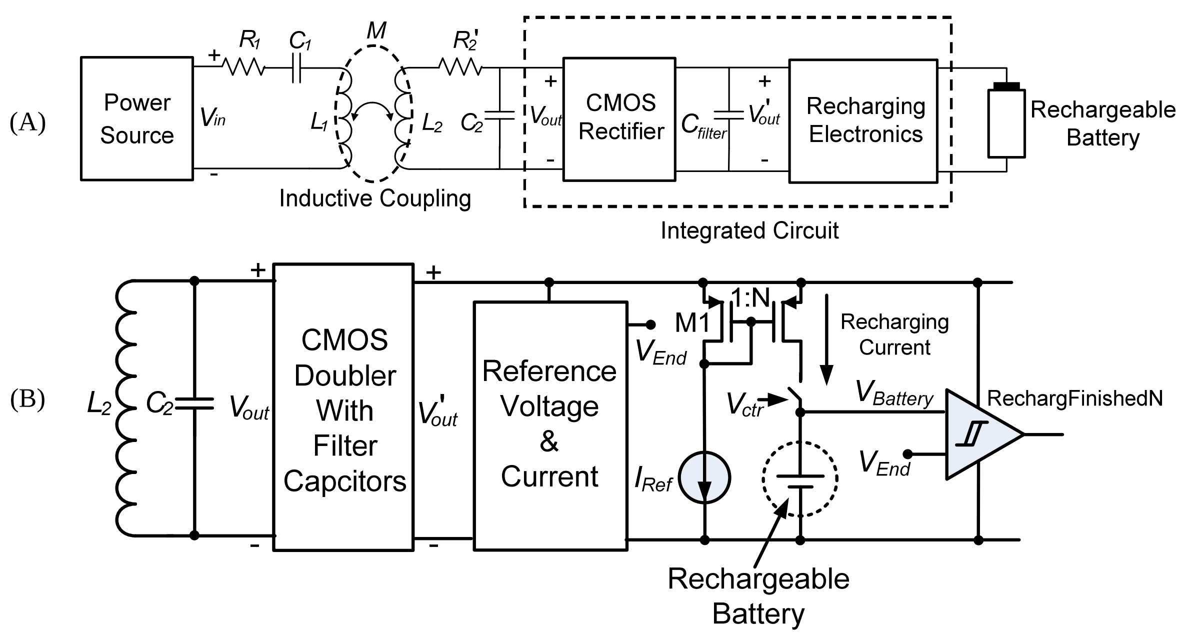

Fig. 4. (A) RF recharging electronics diagram. (B) CMOS recharging electronics.

power management circuitry proposed for use in the WIMM.

Among various available technologies, rechargeable Lithium ion (Li-ion) batteries exhibit the highest energy densities typically in the range of 200–450 Wh/l (watt hour per liter) [9]. For instance, the rechargeable Li-ion QL0003I (from Quallion), with a small volume of only 0.08 cm^3, provides a capacity of 3 mAh and can typically be recharged 3000 times without significant performance degradation. When following a daily wireless recharge regimen, the battery could perform for approximately ten years after implantation. The function of the power management electronics is to efficiently recharge the secondary cell at distances of 10 to 20 cm through body tissue, ensure reliable operation, and avoid overcharging the Li-ion cell, which can lead to electrolyte oxidation and decomposition.

Fig. 4A presents the system block diagram of the overall RF recharging electronics. The RF powering relies on an inductively-coupled electromagnetic link to wirelessly transmit RF power from the external unit to the implanted micromanometer. The RF power is coupled to the tuned internal coil from the external coil through the coils' mutual inductance. The received RF power is then rectified and filtered through the electronics shown in the figure and stored in the onboard battery.

Achieving a high voltage by RF powering over the distance this application requires is one of the engineering challenges involved with the design of this system. Full-wave and half-wave rectifiers are commonly used, but a CMOS voltage doubler rectifier can perform the necessary function with a reduced voltage gain requirement, and is therefore a better choice for this application. Typically, a constant-current mode followed by a constant-voltage mode is required to fully recharge a battery. However, to prolong the battery cycle lifetime, a full battery charge is not desirable. A constant-current recharging scheme is chosen for this application to sufficiently charge the battery to a nominal voltage, replenishing the daily power dissipation within a time period of four hours. Furthermore, constant-current operation minimizes design complexity with reduced circuit power consumption, as well as approximately constant loading impedance on the LC tank in the implantable microsystem; this is desirable to achieve high RF powering efficiency. Fig. 4B presents the diagram of the CMOS recharging electronics. V_{End} and I_{Ref} are generated by a reference voltage and current block. V_{End} is used to determine the end point of the battery recharging voltage, which is designed to be 3.6 V. The recharging current is generated by a scalable current mirror through the reference current, I_{Ref}. A comparator is implemented to compare the battery voltage to V_{End}. The recharging process ends when the battery voltage exceeds V_{End}, and the battery is disconnected from the recharging electronics.

V. Packaging

The sizes of unpackaged devices are typically driven by the relatively large battery and antenna dimensions. After the internal parts are assembled, proper encapsulation of the implant can increase the total volume between 2 and 50 times that of the unpackaged device. The packaging of a medical implant serves two purposes: to protect the device from the host and to protect the host from the device. The packaging must provide mechanical strength to isolate the internal components from undue stress and strain. The device should also be hermetically sealed to prevent water and vapor from permeating into the active system. Finally, it is essential that the outer coating of the device be bio-compatible with the surrounding tissue environment.

VI. Conclusions

This paper proposes an internally-powered, active monitor intended to be implanted in internal organs and transmit data continuously or store it for transmission at convenient time. Onboard power increases the telemetry distance and in effect creates a Holter-type pressure monitor which frees the patient from being tethered to bulky external equipment. Such a device could be implanted via minimally invasive surgical techniques such as endoscopy, cystoscopy, or colonoscopy. A small opening in the mucosa of the bladder or bowel would be created and the device would be implanted into the submucosal space. Placement behind the mucosal lining would prevent stone formation during long-term bladder implantation. A properly designed device could remain chronically implanted, with periodic battery recharge via radio transmission. The advantages offered by this wireless sensor platform can be extended to include other physiological systems as well, with or without slight modifications to the sensor type or packaging.

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