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ASIC Design for Wireless Surgical MEMS Device and Instrumentation

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Abstract—**There is an increasing demand on computerized surgical instrumentation and implants that can acquire intra-operative or in-vivo data for surgeons and engineers. The sensory system is gaining complexity in order to obtain more accurate measurements. Although many off-the-shelf components and chips exist, multiple components are often required to achieve the desired function. Since space is limited in biomedical applications, application specific highly compacted integrated circuits are preferable. In this study, a chip is designed to process an array of microcantilever readout used in an intra-operative soft-tissue balancing instrument.**

Index Terms **– Biotelemetry, data acquisition, wireless sensors, ASIC, MEMS sensors**

I. Introduction

Despite the rapid development of *in vivo* telemetry sensors in the biological and physiological areas [1]-[4], only a small number of these systems have been designed for orthopedic applications. In order to obtain accurate and sophisticated measurements, a microcontroller (MCU) based architecture where data acquisition and signal processing are required prior to transmission, is necessary.

The early published research on using sensors and biotelemetry in orthopedics focused on obtaining *in vivo* data from Total Hip Arthoplasty (THA) patients [5]. Bergmann embedded strain gages into the neck of the femoral component of hip prostheses to measure strain of the patients postoperatively. The instrument is powered by inductive coil. The data are sent using a radio frequency (RF) system embedded in the femoral component [6,7].

D'Lima et al. separated a tibial prosthesis into upper and lower halves, with the upper portion acting as a load cell [8]. Four supports connect the upper and the lower halves with four strain gages sandwiched at their respective supports. The electronics and the telemetry components are embedded into the stem of the prosthesis [8]. This system is inductively powered using a coil worn around the leg of the subject and the data was collected via a wireless RF system.

In addition to instrumented implants, researchers have investigated the use of sensor systems to obtain quantitative feedback intra-operatively by monitoring the compartment pressure. In 1998, Wallace et al. used Tekscan K-scan sensor to assess the tibiofemoral intra-operative contact stresses [9]. Wasielewski et al. used a pressure mapping system from Novel and attached it to the proximal surface of the tibial trial component with silicone adhesive. It was used intra-operatively for soft tissue balancing [9]. Crottet et al. developed a force sensing device for ligaments balancing. It consists of a sensitive plate on each femoral condyle and a tibial base plate. Each plate has 3 deformable bridges with thick-film piezoresistive strain gages. The instrument was tested by a surgeon in a cadaver experiment [10].

The limited space of the implant or instrument posted restrictions on the system design. The number of sensors is also limited. Increasing the amount of sensors complicates the data acquisition, results in excessive wiring, and causes difficulties with the implementation of the telemetry system.

The progression to microelectromechanical systems (MEMS) can potentially solve these limitations. The minimization of the sensing units allows more sensors to be packaged; and the redundant information can be acquired to minimize errors.

Initially, strain-sensing MEMS devices were used to measure residual stress during fabrication and packaging [11]. There is a growing interest in tactile sensing MEMS arrays, which are used for grasp force control, and artificial skin for robots [12,13]. Xu et al. have fabricated a flexible tactile sensor that can be wrapped around a cylindrical robot finger [14]. MEMS sensors are usually embedded inside a composite, which can act as a stress shielding material and change the boundary conditions of the system. The inherent nonlinearity and residual stress from the MEMS devices, the percentage variation of the elements in the composite, and the method used to form the composite are also factors that can affect the sensor performance.

Electronics are necessary to acquire and condition the data from the MEMS are a crucial component to a successful sensing system. Most of the ligaments balancing systems described above utilize multiple surface-mounted off-the-shelf components. However, only a few functions within the component are needed and the working space for biomedical application is limited. It is desirable to have one IC with all the necessary functions. The goal of this study is to develop an Application Specified Integrated Circuit (ASIC) to acquire data from an array of sensors, and prepare the data for the transmitter (TX).

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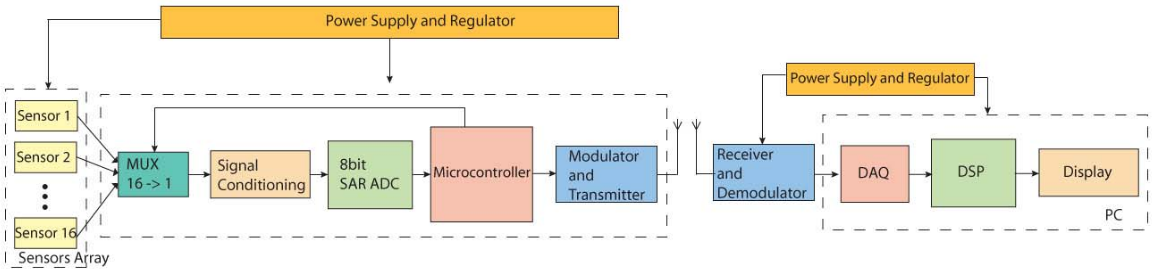

Fig. 1 System architecture

II. Methods

A. Hardware Overview

An initial prototype of the system was designed to identify the building blocks (Fig. 1). Piezo-resistive microcantilever is chosen as the strain sensor. In order to obtain information from each sensor, an analog multiplexer (MUX) is applied between the readout and the signal conditioning circuit. A power regulator is used to reduce DC power noise and regulate the voltage to 3.3 V. The MCU is the main control center of the electronics system. The signals from the MUX are conditioned by a low pass filter and amplifier. It is then converted to digital signal through analog-to-digital converter (ADC) and modulated at the TX before transmission. A receiver (RX) acquires the transmitted signal, demodulates and reconstructs it into a compartment pressure profile.

B. Components Testing

A scaled-up prototype of the system was built with off-the-shelf components. Printed circuit boards (PCB) were made to test the different building blocks above. Micro-cantilevers were purchased from Nascatec (Munich, Germany). The bridge circuit was built onto the microcantilever during fabrication. The microcantilevers were mounted and wirebonded onto the pads of the PCB. The pads were connected to a dual 16-channel-to-1 analog MUX (ADG726, Analog Devices). An ultra low-power 16bit MCU (MSP430, Texas Instrument) is used to test the features necessary for the ASIC design.

A crystal referenced phase lock loop (PLL) transmitter (MAX1472, Maxim-IC) modulates the incoming signal with Amplitude Shift Keying (ASK) and transmits the data at 433.92MHz with a data rate of 100kbps. The RX (MAX1473, Maxim-IC) is used in detect, receive and demodulate the transmitted signal.

The TX and RX were tested by submitting digital data from UART to the TX. The TX and RX were placed 2 meters apart and the transmitted and received signals were compared. The sensitivity and bit error rate were also assessed, which are -115.6 dBm and 0.2% respectively. The specification of the system is shown in Table 1.

Table 1 System specification

Analog input channels	16
A/D Converter input range	0.5 - 3V
A/D Converter resolution	8bit
Linear range of microcantilever	0 - ~3MPa (w/ ~ 1mm thick of EP30MED)
Power supply	3.3V (5V with power regulator)
Carrier frequency	433.92MHz
Transmission power	Adjustable up to 10mW
Data Rate	100kbps max.
Range	Up to 10m
Modulation	ASK
Output method	RS232C
Error checking	Parity bit evaluation
Interface between receiver & PC	GPIB, Serial

C. ASIC Design

Based on test results from the PCB prototype, the following functions were included in the ASIC: signal detection, conditioning, amplification, MUX, and ADC. Typically, the instrument is used for 10 – 15 minutes during surgery. Therefore, the ASIC was designed to use battery power (CR2032, Panasonic). The schematic of the IC design is shown in Fig. 2.

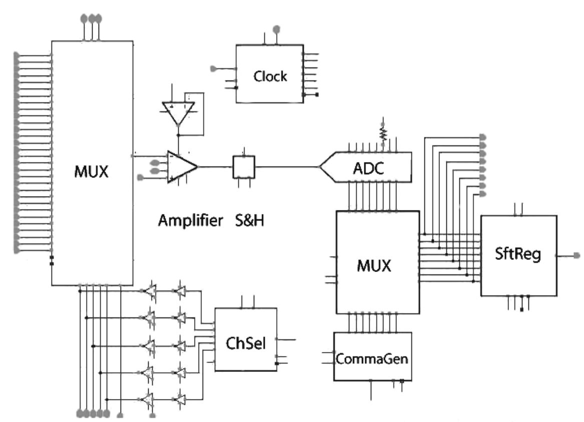

Fig. 2 Schematic of the ASIC design

The MUX was incorporated into the design of the ASIC. The gain of the amplifier is adjustable using an off-chip resistor. A low pass filter is designed according to the Sallen-Key topology. An instrumental amplifier is used to amplify the signal. A sample and hold (S&H) circuit is used to store the analog value output from the amplifier for a short period of time while the ADC is converting the signal. An 8-bit Successive Approximation Register (SAR) ADC was implemented because it has good resolutions and a wide range. A high-resolution comparator was designed for this application. It should have the ability to distinguish the minimum triggering signal with common mode voltage changing from 100 mV to 2 V. The sampling rate of the ADC is dependent on the oscillator. There are 256 quantization levels with a precision of 7.4mV. A comma generation circuit was also implemented into the IC. This is important for the RX since it needs to identify the beginning of the data string.

The chip was designed with Cadence software package (San Jose, CA). It was fabricated through MOSIS using TSMC 0.35 μm CMOS technologies, and is packaged in TQFP package. The design was simulated to ensure proper chip function. The ADC was tested by simulating the conversion of a sine wave by the SAR circuit. Fig. 3 shows the result of the simulation. It takes less than eight clock cycles to arrive at the hold signal.

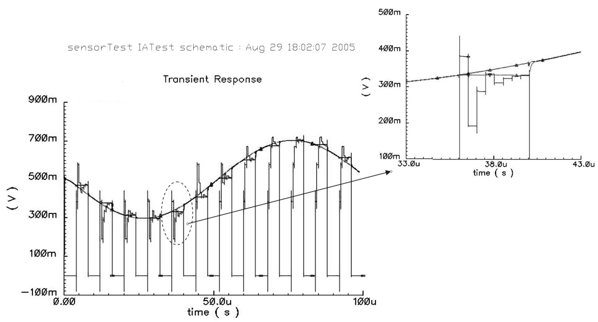

Fig. 3 SAR ADC simulation

III. Results

A PCB was designed to test the fabricated ASIC, shown in Fig. 4. Four chips were tested with two using a 32.768 kHz oscillator and two using a 1.544 MHz oscillator. The clock network output (sample and hold, shift register, and transmitter) performs well. The frequencies of 5 bits addressing signals of the MUX are 42.89 kHz, 21.44 kHz, 10.72 kHz, 5.36 kHz and 2.36 kHz. The amplifier performance was also measured. The open loop gain of the amplifier is ~60 dB. It has a unity gain bandwidth greater than 2.4 MHz and the phase margin is approximately 45°. The sample and hold circuit, which is critical to the performance of the ADC, was tested with input ranging from 200 mV to 2.4 V for a 3.3 V power supply. It also performs well, as shown in Fig. 5.

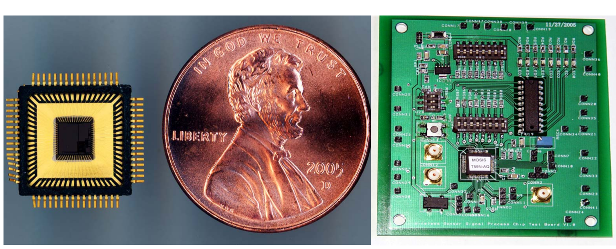

Fig. 4 ASIC (Left), Testing board for the fabricated chip (Right)

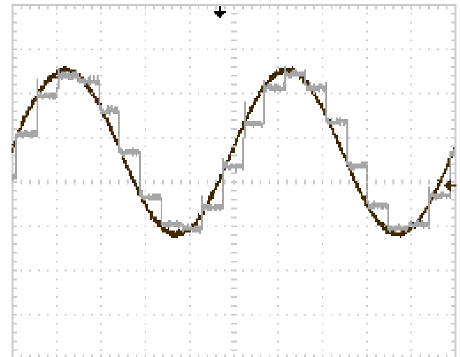

Fig. 5 S&H of a 10kHz Sine wave (Black: input signal ; Gray: signal after sample and hold)

The performance of the ADC on the chip was also measured. Fig. 6 shows a linear relationship between the analog voltage and its corresponding digital output. The black line indicates the ideal transfer function and the white line represents the collected data. There is a sudden jump at 700 mV due to a complete switch of the digital signal (from 01111111 to 10000000). The DNL and INL of the ADC were tested. The result is mostly linear except for the point where the complete switch of the signal occurs, as indicated by the high spike in the DNL and the jump in the INL (Fig. 7). The conversion of the sine wave is shown in figure 8.

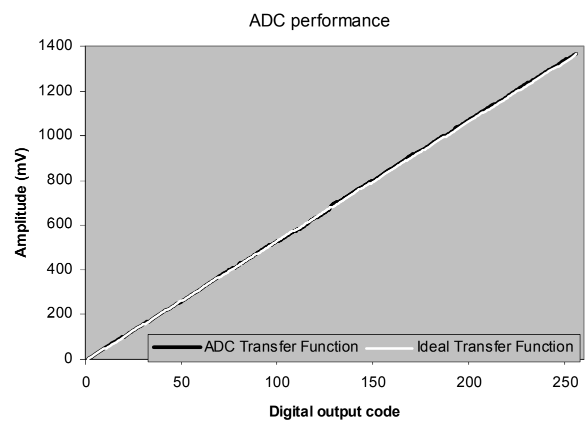

Fig. 6 ADC performance

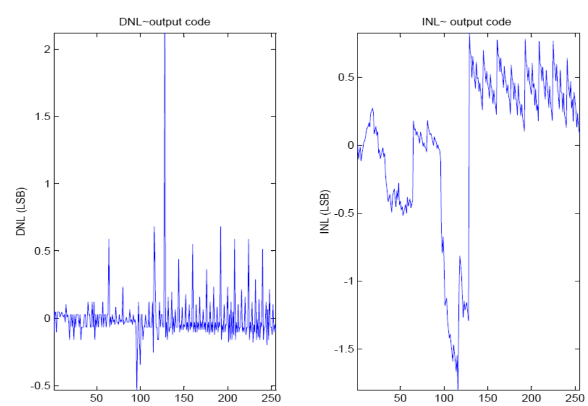

Fig. 7 Measured DNL and INL of the ADC

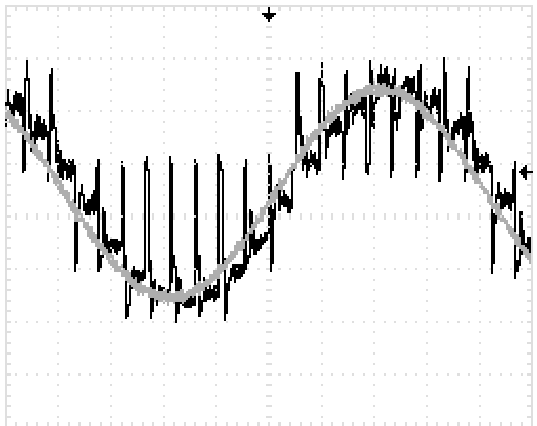

Fig.8 ADC of 5kHz sine wave (Gray: input signal; Black: SARADC)

IV. DISCUSSION

In order to satisfy the need to acquire more information with limited working space, eliminating unwanted components and extracting necessary building blocks for the system is necessary. ASIC allows us to compact these functions into one single chip. Hence, it becomes possible to use more sensors in the system. The ADC is the most important and difficult design in this ASIC, but the fabricated chip shows excellent results. Moreover, all the building blocks perform according to the specification. Currently the chip supports 16 input channels. Thus, one chip is needed for each side of the femoral condyle. The output signal can be time division modulated, or it can potentially use two frequencies for transmission.

V. CONCLUSION

The ultimate goal for this research is to develop a spacer block that can provide quantitative feedback to a surgeon concerning the balancing of the soft tissue during total knee arthoplasty. The entire system will be encapsulated within a FDA-approved bio-compatible epoxy material. Due to the unknown factor of the composite stress shielding, the microcantilever is currently being optimized. Future iteration of the chip will integrate the transmitter into the system. The design and layout of the chip is being optimized to minimize the analog, RF and digital noise.

Even though the microcantilever is ideal for measuring axial stress, it is not suitable for implantable use. Implants experience stresses from all directions. It could possibly wear out the protective layer and expose the sensor, and silicon is a potentially hazardous material to the human body. A capacitive MEMS device that is capable of measuring all three axial and shear forces fabricated with bio-compatible material is being investigated. The technology used in this study can be extended into the design of an ASIC for the multi-directional sensors.

REFERENCES

[1] R.S. Mackay and B. Jacobson (1961): ‘Radio telemetering from within the human body,’ Science, vol. 134, pp 1196-1202, 1961

[2] B. Ziaie, M.D. Nardin, A.R. Coghlan, and K. Najafi (1997): ‘A single-channel implantable microstimulator for functional neuromuscular simulation,’ IEEE Trans. Biomed. Eng., vol 44, pp. 909-920

[3] M.C. Shults, R.K. Rhodes, S.J. Updike, B.J. Gilligan and W.N. Reining (1994): ‘A telemetry-instrumentation system for monitoring multiple subcutaneously implanted glucose sensors,’ IEEE Trans. Biomed. Eng., vol 41, pp. 937-947

[4] B.D. McKean and D.A. Gough (1988), ‘A telemetry-instrumentation system for chronically implanted glucose and oxygen sensors,’ IEEE Trans. Biomed. Eng., vol BME-35, pp. 526-532

[5] Bergmann G. Graichen F. Rohlmann A.(1990): ‘Instrumentation of a hip joint prosthesis. In: bergmann G, Graichen F, Rohlmann A (Eds.).’ Implantable Telemetry in Orthopaedics. Forshungsvermittlung der Freien universitat, Berlin, 35-63.

[6] Graichen F, Bergmann G. (1991): ‘Four-channel telemetry system for in vivo measurement of hip joint forces.’ J. Biomedical Engr 13, pp.370-374.

[7] Bergmann G. Hip Joint Loading During Walking and Running Measured in Two Patients, Journal of Biomechanics 26 (8): 969-990, 1993.

[8] D’Lima DD, Townsend CP, Arms SW, Morris BA, Colwell CW. (2005) ‘An implantable telemetry device to measure intra-articular tibial forces.’ J Biomechanics 38, pp. 299-304

[9] Wallace AL, Harris ML, Walsh WR, Bruce JM, (1998) ‘Intraoperative Assessment of Tibiofemoral Contact Stresses in Total Knee Arthroplasty’, J. Arthroplasty, vol 13, no. 8, pp923-927

[10] Wasielewski R.C., Galat D.D. Komistek R.D. (2004): ‘An Intraoperative Pressure-Measuring Device Used in Total Knee Arthroplasties and Its Kinematics Correlations’. Clin Orthop. 427: 171–178, 2004.

[11] Denis Crottet, Thomas Maeder, Daniel Fritschy, Hannes Bleuler, Lutz-P. Nolte, and Ion P. Pappas (2005): ‘Development of a Force Amplitude- and Location-Sensing Device Designed to Improve the Ligament Balancing Procedure in TKA’ IEEE Trans. Biomed. Eng.

[12] Kane BJ, Cutkosky MR, Kovacs GTA (2000), ‘A Traction Stress Sensor Array for Use in High-Resolution Robotic Tactile Imaging’, J. MEMS, Vol 9, no.4, pp. 425-434

[13] Yamada D, Maeno T, Yamada Y (2002), ‘Artificial Finger Ski n having Ridges and Distributed Tactile Sensors used for Grasp Force Control’. J. Robotics & Mechatronics, vol 14. no.2, pp141-146

[14] Xu Y, Tai YC, Huang A, Ho CM (2003),’IC-Integrated Flexible Shear-Stress Sensor Skin’, J. MEMS, Vol. 12 no.5,pp740-747