Multi-channels wireless strain mapping instrument for total knee arthoplasty with 30 microcantilevers and ASIC technology

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***Abstract*—A wireless strain mapping instrument was developed for soft tissue balancing in both traditional and minimum invasive total knee arthroplasty. The sensing element consists of an array of 30 microcantilevers, which are encapsulated with medical grade epoxy. An ASIC was developed to process the data, which includes a 32-to-1 multiplexer, instrumentation amplifier (IA), sample and hold circuit, 8bit SAR ADC, on chip voltage reference and a digital control circuit. A transmitter and receiver operating at 433.92 MHz were used to interface the instrument and the computer. The microcantilevers were rebalanced with a series of resistors after the encapsulation. The thickness of the epoxy governs the sensitivity of the strain experienced by the microcantilever. The relationship between load and strain is optimized to be linear from 0-300kPa, which is well within our range of interest.**

I. INTRODUCTION

Total knee arthroplasty is one of the most common practices of joint replacement procedure world wide today. It is to relieve pain from patients who has osteoarthritis on their knee joints. With the constant improvement and evolution for the design of the implants, better material selections and sophisticated computer assisted surgical navigation system have provided help to the surgeons. However, early failure of the implant is still commonly observed. Most of the failures are due to the malalignment of the femoral and tibial components and the tension imbalance between the medial and the lateral cruciate ligaments. If the patient has valgus/varus deformity, a correction has to be made to ensure proper alignment. A recently introduced minimum invasive surgical technique further limited the visibility as the joint is partially exposed; hence, reducing the accuracy of the bone resections.

Various instruments have been designed as a qualitative verification tools, which often depends on the surgeons' experiences. Previous researches have embedded 4 strain gages into the tibia component to assess post-operative kinematics [1]. One of the major challenges is to develop and minimize the size of the sensors as well as the electronics such that they can be fit into the instrument or prosthesis. While putting a large sensor array can provide important information about the pressure mapping between the joints, yet with a trade off of complicated electronics and computational cost, making real time measurement difficult. A system with fewer sensors, however, can suffer major information lost if any one of them malfunctions. The goal with this research is to develop and embed a wireless strain mapping sensor array, which can provide quantitative feedback to the surgeon.

II. SYSTEM IMPLEMENTATION

The current system is developed to be embedded into a spacer block instrument. The overall system functional diagram is shown in figure 1.

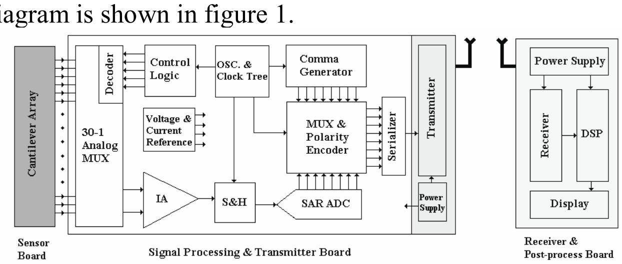

Figure 1. Overall system archeiture

A. Sensors board

The sensor board consists of 30 piezoresistive microcantilevers (Nascatec, Munich) as strain sensing element with 15 of them on each condylar compartment and 1 additionally microcantilever as thermo-compensation. The sensors have to be encapsulated with medical grade epoxy for protection and create a bio-compatible interface between the instrument and bone tissues. Four types of medical grade

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epoxies (EP30MED, EP21LV, EP42HT-2 and EP3HT) by Master Bond (Master Bond Inc., NJ) that are Class IV approved by the FDA were tested. EP30MED is the optimal choice for encapsulation material as the other three have either high viscosity, limited working time window, or produce a large amount of bubbles during the curing process.

Simulations were done in Coventor (Coventor, Inc., Cary, NC) to determine the amount of epoxy required to adjust the sensitivity of the sensors. According to previous studies by Wasielewski [2], the intra-operative compartmental pressure is between 30 - 150 kPa. The FEA simulations shown that 2mm EP30MED would place that range within the linear region of the sensor.

The sensor was then characterized by encapsulating within 2mm of epoxy and tested under the Instron tensile testing machine. A Wheatstone bridge was fabricated onto the microcantilever. However, the bridge became imbalance possibly due to the shrinkage and the weight of the epoxy itself. A parallel balancing resistor is used to rebalance the readout circuit. A force sensitive resistive (FSR) sensor was also encapsulated within the epoxy as comparison. They were loaded at 20µm/minute and are connected to their readout circuits respectively. Eight trials were performed and the result is shown in figure 2. The black line represents the 300kPa range. The FSR was saturated at the early stage. The characterized properties of the microcantilever are shown in table 1.

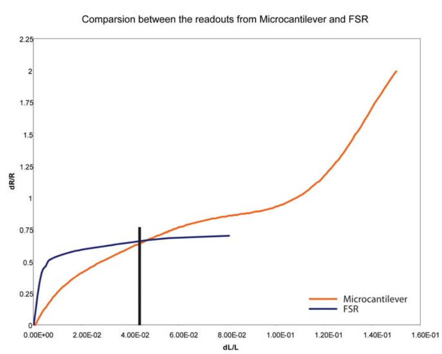

Figure 2. Comparison between the average readout from microcantilever and FSR

TABLE I. PROPERTIES OF MICROCANTILEVER ENCAPSULATED IN 2MM OF EP30MED

Parameter	Value
Range	0 – 300 kPa
Input	0 – 3.3V +/- 1%
Linearity	0.625mV/kPa (over range)
Repeatability	0.6444mV/kPa (over range)
Sensitivity	0.35455mV/kPa (over range)

All 30 sensors were wire bonded onto a 0.020" printed circuit board in a half bridge configuration and the thermo-compensation microcantilever was used to complete the bridge as shown in figure 3.

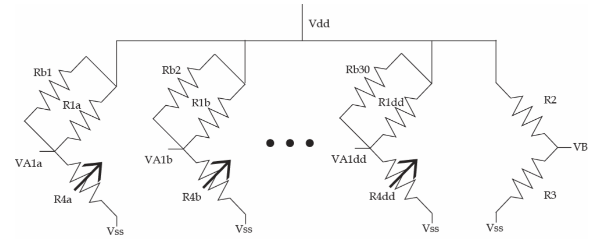

Figure 3. Schematic for the readout circuit for the microcantilevers (R4x) and the balancing resistors (Rbx)

B. Electronics board

The readout circuit was tested with commercial available components. Due the limited space of the instrument, an ASIC was developed for this application. The middle block in figure 1 shows the major components of the signal processing functions.

a) Analog multiplexer

A 32-1 multiplexer (MUX) was implemented with 30 channels for sensor inputs and 2 channels for comma signals. The comma signal is used to determine the beginning of the signal after it is being sampled into the computer. The MUX consists of a 5-bit decoder, which receives signals from the digital control circuit and control the on and off of the analog switches. A dummy switch is also implemented for the common signal from the thermo compensating microcantilever.

b) Instrumentation Amplifier

The instrumentation amplifier (IA) was implemented to amplify the differential signals from the sensors to the full scale (FS) and reject the common mode signal [3]. The classic 3 opamps configuration was used for the IA as shown in figure 4. The output DC voltage is set to the middle of input range of the next stage, sample and hold, which is 1.05V in this design.

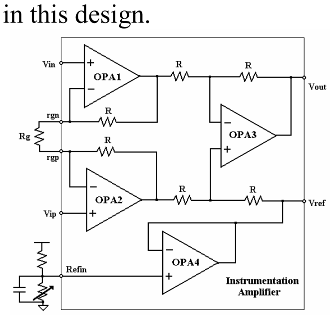

Figure 4. Instrumentation amplifier schematic

c) Voltage and current reference

An on chip voltage reference is required to provide a stable reference for the ADC. Bandgap voltage reference is chosen as it is independent from process, power supply and temperature (PVT). The reference is generated by adding a negative Temperature Coefficient (TC) voltage (base-emitter junction voltage) and a weighted positive TC voltage (thermal voltage). Zero TC can be achieved by adjusting the value of R_2 and R_1 based on the following equation

$$V_{BG} = V_{be} + \frac{R_2}{R_1} V_T \ln k \tag{1}$$

where, Vbe is the base-emitter pn junction voltage, VT is thermal voltage and k is the geometry ratio of Q1 and Q2. The bandgap reference circuit is shown in figure 7. The current reference for the current-steering DAC cannot be fully generated on-chip due to the lack of a high precision absolute value resistor. With the aid of a low TC, high precision external resistor, and bandgap voltage reference, an accurate current reference can be obtained. The current reference circuit is shown in the lower part of figure 5.

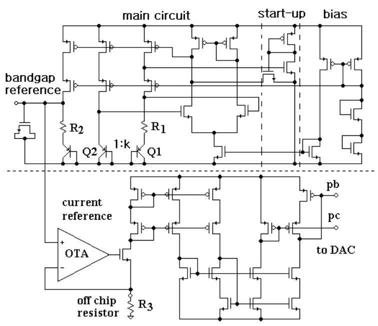

Figure 5. Bandgap voltage reference schematic

d) Sample and Hold

The sample and hold (SH) was inserted between the IA and ADC to grab and store the fast changing signal into the sampling capacitor Cs. However, the thermal noise is also trapped into the capacitor during the turning off of the switch. For an 8-bit ADC, the minimum required sampling capacitor Cs can be calculated by the following equation

$$C_S = n_f \frac{k_B T}{V_n^2} \tag{2}$$

where, k_B is Boltzmann constant, T is absolute temperature, V_n^2 is quantization noise power, and the coefficient n_f models the noise from the amplifier and has a value between 0~1. In (2), we assume that the quantization noise power is equal to the thermal noise power. The settling error for linear one pole settling is expressed as

$$\varepsilon_r = e^{-\frac{\omega_{-3dB}}{2f_S}} = e^{\frac{-1}{2f_S R_S C_S}} \tag{4}$$

where, f_S is sampling frequency and R_S is the equivalent on-resistance of sampling switch. The maximum allowed settling error for 8-bit ADC is 0.39%. Then the equivalent resistance for the switch can be calculated by

$$R_S = \frac{1}{2} \frac{1}{f_S C_S \ln \frac{1}{\varepsilon_r}} \tag{5}$$

where, ε_r is settling error. Once the minimum equivalent on-resistance of the switch is determined, the switch size can be determined by the transistor parameters. A half size dummy switch M2 in series with the main sampling switch M1 was also implemented to partially cancel the charge injection M1. The schematic is shown in figure 6.

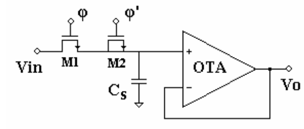

Figure 6. Sample and Hold schematic

e) SAR ADC

The successive approximate register ADC was used as it is suitable for moderate speed and moderate resolution application. It is also power and area efficient. The SAR ADC consists of a high resolution comparator, SAR logic and DAC. The schematic is shown in figure 7. The SAR ADC takes 8 periods to convert and 1 period of sampling. An extra bit of parity check was added after the LSB is resolved.

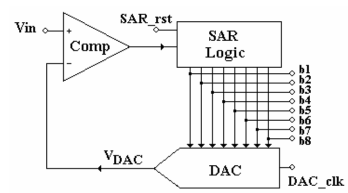

Figure 7. SAR ADC Schematic

In order to achieve fast settling and avoid meta-stability, a regenerative latch is implemented into the two-staged cascaded pre-amplifier as shown in figure 8.

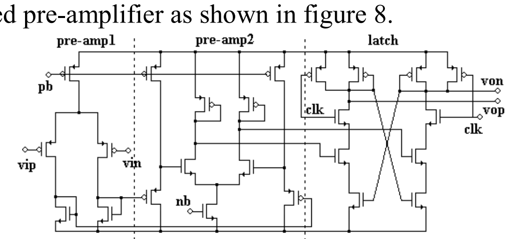

Figure 8. Comparator Schematic

The chip was fabricated in a 0.35μm 2-poly 4-metal process. The area for the core circuit is 1.54 mm^2. The chip micrograph is shown in figure 9.

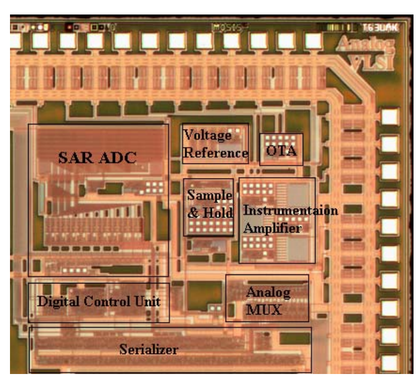

Figure 9. Chip micrograph

The performance of the ASIC was evaluated and is shown in table 2.

TABLE II. ASIC PERFORMANCE SUMMARY

Parameters	Values
Analog input channels	30
Analog MUX switching frequency	Oscillator dependent
A/D Converter input range	~ 200mV – 1589mV
A/D Converter resolution	8bit
A/D Converter rate	772 kHz
Band gap reference	1.249V
INA gain	Gain resistor dependent
INA phase margin	65^{o}
INA Unit gain bandwidth	~ 2.4 GHz
A/D ENOB	7.24 bit
A/D SNDR	45.4 dB
A/D SFDR	56.4 dB
DNL	+0.57/-0.42 LSB
INL	+1.3/-0.2 LSB
Power supply	2.6 – 4.4V
Error checking	Parity bit evaluation
Power	17.8 mW

C. wireless board

A wireless component is added to the system for the communication between the instrument and the computer. A 433.92MHz ASK wireless chip (MAX1472) is used due to its small package size. A chipped antenna (Tricome, Taiwan) was used. The PCB was fabricated with rogers 4350.

For the overall system two rechargeable Poly-Li-ion batteries was used for the prototype. Two high density sockets were used to connect the sensors boards to the electronics boards. The system is shown in figure 10. The overall thickness of the system is roughly 18mm with the batteries being the biggest limitation.

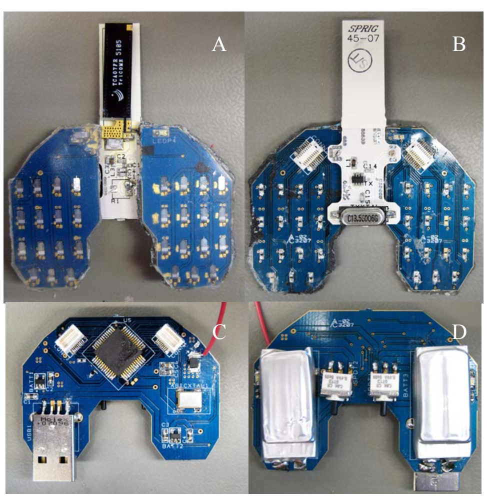

Figure 10. Prototype of the strain sensing instrument. A: Top view of the sensors and transmitter board. B: Bottom view of the sensors and transmitter board. C: Top view of the eletronics board. D: Bottom view of the eletronics board.

The data was acquired and re-sampled by the receiver board into the computer (figure 11). The clock of the system is re-synchronous based on the knowledge of the comma signals and the data is decoded and reconstructed.

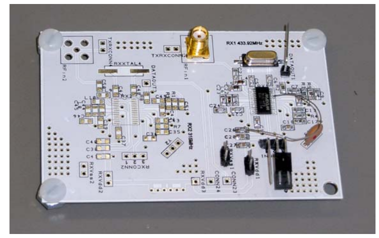

Figure 11. Receiver board for the system

III. DISCUSSION

The overall error of the system was determined to be +/- 8.29mV, which is approximately +/- 1.79kPa. One of the challenges to this design is the encapsulation process of the microcantilevers. Four of the sensors were lost after the encapsulation. It is suspected that the shrinkage of the epoxy disconnected the wirebonds between the sensors and the PCB. Secondly, the microcantilevers have to be individually re-balanced after encapsulation, which is less than ideal for mass production. A power-on self-adjusted DAC can potentially solve the problem by calibrating the balancing resistor in a binary search fashion. All 31 microcantilevers consumes 0.23mW of power. Further means of increasing the mapping resolution will require separate powering control to reduce the overall power consumption. The current decoding program was written with MATLAB and has a refreshing rate of the system 7 frames/sec. It can be drastically improved once it is migrated to C++.

This research demonstrates the methodologies and capability to integrate MEMS sensor and ASIC technology to be used for medical monitoring device. Even though this is designed based on the idea of a spacer block, it can be applied to other instruments as well.

ACKNOWLEDGMENT

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