Monitoring Of Post-Operative Bone Healing Using Smart Trauma-Fixation Device with Integrated Self-Powered Piezo-Floating-Gate Sensors

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Abstract— Objective: Achieving better surgical outcomes in cases of traumatic bone fractures requires post-operative monitoring of changes in the growth and mechanical properties of the tissue and bones during the healing process. While current in-vivo imaging techniques can provide a snapshot of the extent of bone-growth, it is unable to provide a history of the healing process which is important if any corrective surgery is required. Monitoring the time-evolution of in-vivo mechanical loads using existing technology is a challenge due to the need for continuous power while maintaining patient mobility and comfort. Methods: This paper investigates the feasibility of self-powered monitoring of the bone-healing process using our previously reported piezo-floating-gate (PFG) sensors. The sensors are directly integrated with a fixation device and operate by harvesting energy from micro-scale strain variations in the fixation structure. Results: We show that the sensors can record and store the statistics of the strain evolution during the healing process for offline retrieval and analysis. Additionally, we present measurement results using a biomechanical phantom comprising of a femur fracture fixation plate; bone healing is emulated by inserting different materials, with gradually increasing elastic moduli, inside a fracture gap. Conclusion: The PFG sensor can effectively sense, compute and record continuously evolving statistics of mechanical loading over a typical healing period of a bone, and the statistics could be used to differentiate between different bone healing conditions. Significance: The proposed sensor presents a reliable, objective technique to assess bone healing progress and help decide on the removal time of the fixation device.

Index Terms— Bone healing monitoring, self-powered piezo-floating-gate (PFG) sensors, smart trauma-fixation device.

I. INTRODUCTION

Traumatic bone fractures caused by traffic injuries account for a significant portion of visits made to the emergency department (ED). For instance, in the year 2011, approximately 250,000 ED visits were attributed to traumatic fractures that were caused by motor vehicle traffic injuries [1]. Fractures that are sustained in traffic accidents often require the implantation of a fixation device through a surgical procedure. And even though the purpose of the fixation device is to hold bone fragments together and facilitate the healing of the bone, for many reasons the healing process can fail, resulting in the non-union of the bone. It was reported in [2], that the occurrence of non-union could be as high as 10% for all cases of fractures and could be as high as 50% for open fractures of the tibia. Fracture healing is usually assessed subjectively based on radiography, which unfortunately has been shown to be inaccurate due to the non-correlation between the amount of callus (material that bridges the bone fragments) and the stiffness of the bone [3], [4]. In such cases, early removal of fracture-fixation devices can lead to the re-fracture of the healing bone. Therefore a more reliable objective technique has to be used to determine the adequate removal time of the fixation device.

Many techniques have been proposed to assess bone healing using ultrasonic wave propagation, changes in electrical properties of bones and callus stiffness measurement. Ultrasonic wave propagation has been used to quantify bone fracture healing by measuring the changes in both ultrasound velocity and attenuation [5]-[7]. However, its use for in-vivo measurements is impractical due to the surrounding soft tissues and the lack of evidence connecting ultrasonic measurements to bone stiffness [8]. Methods that use changes in electrical properties (conductance, impedance, etc.) to assess fracture healing require external fixators to apply electric current through the fractured bone [9]. The accuracy of the measurements may be altered by the presence of other tissues. Mechanical stiffness of the callus can be measured either directly by removing the fixation device or indirectly by taking into consideration its stiffness [10]-[12]. However, the direct method requires removal of all the fixation devices and therefore it is only applicable for the later phases of the healing process whereas the indirect method is limited to fracture fixation by external fixators as it measures the deflection of the fixation pin or the deformation of the device [8]. One way to improve indirect stiffness measurement method is to use advanced sensing technologies to monitor orthopedic implant’s mechanical usage. Post-surgery, the load applied to the stabilized bone is typically shared by both the fixation device and the bone. During the initial stage of the fracture healing process, the fixation device carries the majority of the load. As the callus ossifies, the bone takes on the majority of the applied load. Therefore, by monitoring the
changes in the loading conditions of the fixation device, the stiffness of the bone can be inferred. The technical challenge is to be able to continuously monitor the mechanical strain-levels or mechanical usage of the fixation device as it is being used.

Several studies have proposed the use of sensing devices in orthopedic implants to measure in-vivo forces and strains. A strain-gauge hip prosthesis was first introduced in [13] where the strain gauges were wired to an external measuring device. An instrumented total knee implant was developed to measure the dynamic tibiofemoral force and center of pressure [14]. The developed orthopedic implant contained four load cells that were connected directly to a data acquisition system. However, connecting the sensors to external measurement devices limits the mobility of the patient and does not allow for continuous monitoring of the implant under regular loading conditions.

More recent research efforts have been focused on developing telemetry systems for orthopedic implants. Telemetry systems have been incorporated within hip implants [15], [16], knee joints [17], [18], femoral replacements [19], [20], and tibial tray [21] to monitor and transfer in-vivo loads, strains and temperature wirelessly. Most of the developed telemetry technologies comprise on-board energy storage devices (batteries and super-capacitors) for sensing, computation, storage and wireless communication. The use of batteries in biomedical implants is not suitable due to their limited life time, large size and chemical side effects. Thus, an inductive link is typically used as an alternative to remotely deliver power from an external source [22]. However, the approach is limited by the range and the mobility of the patient as the external power source needs to be carried and periodically recharged. This is impractical for continuous, long-term autonomous monitoring. An ideal solution would be a sensor that is seamlessly integrated with the fixation device and that harvests its operational energy directly from the mechanical activity of the implant. In this manner, the sensor can be continuously active and record the implant loading statistics without experiencing any loss of data. In [23] a piezoelectric energy harvesting had been proposed as a method to continuously power sensors for orthopedic implants. While some of these devices (for e.g. sensors for knee implants) could be sized and packaged to harvest the maximum amount of energy from in-vivo compressive or tensile loads, their relatively large form factor [24,25] limits their integration with fixation devices. An implantable self-powered sensing system for orthopedic implants was proposed in [26]. The system comprised of piezoelectric sensors for strain measurements and a radio-frequency telemetry unit for wireless transmission. However, the strain-energy required to activate the wireless transmission was reported to be too large for self-powered sensing of micro-strain variations. Also, proposed system was designed to record instantaneous changes in strain levels and therefore would require an ex-cutaneous receiver for continuous data logging.

In this paper we show that our previously reported piezo-floating-gate (PFG) self-powered sensors [27] can overcome the size and power limitations and can be used for continuous monitoring of the bone healing process. A key feature of the PFG sensor is the use of floating-gate sensing circuits that compute and store cumulative statistics of the strain-rates and stresses while achieving operational power limits not possible with any competing health and usage sensing technology [28]. The sensor requires only nanowatts of power that can be easily harvested from a miniature piezoelectric transducer. This enables battery-less, self-powered PFG sensors to be potentially implanted inside the body or attached to the fixation device. In this paper we investigate the use of the PFG sensor for self-powered monitoring of the evolution of strain during a bone healing period, under cyclic loading, both numerically and experimentally. Even though this study is only performed on femur fracture fixation devices, the technique and the sensor is also applicable to other orthopedic implants (knee joints, hip replacements, etc.).

![Fig. 1. The process of bone fracture healing.](image-url)
II. MODELING STRAIN-EVOLUTION IN A FIXATION PLATE DURING BONE HEALING

The first step in this feasibility study is to determine the magnitude of strain induced on the surface of a fixation device during the fracture healing process. This will be used to determine and optimize the design of the PFG sensor. The healing of a bone fracture consists of three major phases: reactive, reparative and remodeling phase [29]. Fig. 1 displays the steps involved in repair of a bone fracture. The reactive phase starts within a few hours after fracture. A blood clot (hematoma) is formed by the blood released from the damaged blood vessels. Days after fracture, the reparative phase starts. A hyaline cartilage and a spongy bone are developed, respectively, by periosteal proximal and periosteal distal cells. The two developed tissues expand until they unite with both sides of the fracture. A new mass of heterogeneous tissue, known as fracture callus, is created inside the fracture gap, restoring some of the bone original strength. The internal callus forms between the ends of the bone and the external callus forms a collar around the fracture. Then, within the reparative phase, woven spongy bone replaces the internal and external calluses. The hyaline cartilage and woven bone are gradually replaced with lamellar bone in the form of trabecular bone. This process is known as callus ossification. Most of the bone’s strength is restored when trabecular bone replaces all of the woven bone and cartilage of the original fracture callus. During the remodeling process the trabecular bone develops into compact bone and the medullary cavity is restored by removing part of the internal callus. The duration of each phase depends on different factors such as age, nutrition, blood supply, etc. While the process of bone healing could vary between different instances of fracture and subjects, successful bone healing is determined by the ability to reach a certain bone stiffness within a defined period [30]. Delayed union is typically caused by a cessation of the periosteal callus production, however, it can eventually heal by endosteal healing which is defined by a rapid fracture bridging after the cessation of periosteal healing response. Nonunion is therefore indicative of unsuccessful bridging after the cessation of both periosteal and endosteal healing responses [30].

Note that the progression of the bone-healing is a non-linear process and varies across different instances of fracture healing. However, two signatures of bone-healing progression should remain invariant across different instances: (a) during the initial (unstable) phase the fixation-device takes the dominant portion of the mechanical load; (b) during the final (remodeling) phase the fused segment of the bone takes the dominant portion of the mechanical load. So, as the bone heals, the stiffness of the fractured bone increases and therefore the strain levels on the fixation-device should drop significantly. To estimate the level of strains induced in a fixation device during bone healing, a three dimensional model of the bone assembly (fractured bone + fixation plate) was created using SolidWorks (as shown in Fig. 2). The plate, the femur bone and the holding screws were modeled according to the following experimental setup which was based on [31], [32]. An unstable distal femur fracture was modeled by introducing a 12 mm gap osteotomy on a synthetic femur replica according to the procedure described in [31], [32].

Fig. 2. 3D model of the bone fixation assembly using SolidWorks.

Fig. 3. Strain distribution in the implant.

Fig. 4. Experimental and numerical strain evolution.
The gap osteotomy was then stabilized using a periarticular locking plate (10-hole NCB Femoral Plate, Zimmer Inc.). The distal plate segment was applied to the metaphysis using three 6.5 mm locking head screws and the proximal plate segment was applied to the diaphysis using four 5 mm locking head screws.

The model was then imported into the general purpose finite element program ABAQUS in order to numerically investigate the distribution and the variation of the in-vivo implant strains over the healing period. The elastic moduli used to model the bone and fixation plate were 16 GPa and 110 GPa respectively. Linear static analysis was conducted using tetrahedral elements to model the bone and fixation implant. Rigid no penetration contact behavior was defined for the lateral interaction between the plate and the bone. The fixation of the orthopedic implant to the bone was performed using a tie contact between the external surface of the screws and the internal surface of the corresponding threaded holes in the bone. The distal fixture was fixed and a concentrated compression load was applied to the femoral head center. Fig. 3 displays strain distribution along the orthopedic plate. Results show a maximum strain concentration adjacent to the hole located at the centerline of the fracture. Bone healing was simulated by re-placing the fracture gap geometry with a material whose elastic modulus was increased gradually. A comparison between experimentally measured strains using a strain Gauge and numerically computed strains using a FEM analysis is presented in Fig. 4. The applied load was a static force with an amplitude of 420 N. The x-axis represents the elastic modulus of the materials used to fill the osteotomy gap. Results show a good agreement between the computed and measured strain values. When the bone heals, the strain levels drop to approximately 50% of the initial values. The result shown in Fig. 4 also shows that the levels of strains are in the order of 100 με or less. In [30] we had shown that for such levels of strain variations with loading frequency of less than 1 Hz, the power that could be harvested using a typical piezoelectric transducer is in the order of a few hundred nanowatts. This makes the setting ideal and attractive for the use of PFG sensors.

III. PFG BASED SELF-POWERED SENSING AND DATA LOGGING

A. Operational Principle of PFG Sensing Device

The working principle of the PFG sensor is illustrated using a simplified energy-band diagram in Fig. 5(a) where the piezoelectric transducer converts the energy in the mechanical strain variations into high-energy electrons (or hot-electrons) in the channel of a MOSFET transistor [33]. If the energy of some of these electrons (with the right momentum vector) exceeds the energy barrier (3.2eV) of the silicon, silicon-dioxide interface (as shown in Fig. 5(a)), these electrons surmount the barrier and get trapped onto the floating-gate. Because the floating-gate is electrically isolated by high quality insulating oxide, the injected electrons remain trapped for a long period of time. As the piezoelectric element is periodically excited, more electrons are injected onto the floating gate and the total amount of charge on the floating gate indicates the duration and extent of the mechanical disturbance. The beauty of this physics-based sensing approach is that it completely eliminates the need for voltage regulation, energy storage, analog-to-digital converters (ADCs), micro-controller units (MCUs) and random-access memories (RAMs) and hence can be used to push the fundamental limits of self-powered sensing. The PFG self-powering device has been shown capable to operate at pico-watt (10^{-12} \text{ – } 10^{-9} \text{ W}) power dissipation levels, with its response remaining invariant for mechanical strain-levels down to a few micro-strains (με) [35]. This enables the PFG device to potentially self-power, sense, compute and store at the fundamental limits of strain-energy that can be harvested from biomechanical structures.

The floating-gate also acts as a non-volatile memory for storage from which data could be retrieved offline for analysis. The generic system level architecture of a PFG sensor can be viewed as a schematic shown in Fig. 5(b) where an interface circuit connects the piezoelectric transducer with the floating-gate memory bank. By modifying the topology of the interface circuit, the sensor can be programmed to record statistics of different levels of strain [34] or different rates of strain [36]. Because read-out and initialization of the floating-gates require a more precise calibration and control, the functionality is achieved using a different source of energy as shown in Fig. 5(b). This source of energy could be delivered either using a plug-and-play cable [35], or using a radio-frequency telemetry link [34] or using an ultrasonic telemetry link [38]. The objective of this paper is to investigate the use of PFG based self-powered sensor to monitor bone-healing. Therefore, we have used a simple plug-and-play link to initialize and retrieve data from the floating-gates.

B. PFG Architecture and Fabricated Circuit

Fig. 6 shows the architecture of the PFG sensor integrated circuit (IC) which has been used for this study. It consists of seven PFG sensing channels (henceforth: PFG injector array), each with an independently controlled activation threshold dependent on the Voltage Reference and controlled through the Injection Control. Fig. 6 also shows the basic circuits for some of the key modules of the IC. Many of these circuits have been previously reported [33]-[39] and the details have been omitted here for the sake of brevity. The data-logging mode components that are powered by the piezoelectric transducer are highlighted in blue, and the programming mode components that are powered by an external source are highlighted in red. Blocks that are do are not contained within a highlighting box may be active during either mode of operation.

The programming mode is used to tune and calibrate the system to a known state before connecting it to operate with a piezoelectric material as the power source. During this mode, an external supply can be used to activate the Injection and Tunneling Charge Pumps to generate the necessary voltages.
for impact-ionized hot-electron injection and Fowler-Nordheim tunneling [33]. Using the aforementioned methods, the charges on each of the floating gates in a PFG array (a single channel of which is shown as the inset to the Injection Control block) are set to create a uniform voltage, as measured on the Pulse Encoder output. Also contained in the programming mode components are a simple Digital Interface to control the activate channel, out of the seven in the array, that is active for reading out or programming.

In the data-logging mode, the components highlighted in red on Fig. 6 lay dormant, and only those highlighted in blue or non-highlighted are utilized. The only source of power in this mode of operation is the external piezoelectric transducer which drives the Time Dilation circuitry used to spread and conserve the energy generated by actuation to allow for extended dynamic range of the PFG sensor, as first described in [36] and later validated in practical applications as presented in [38], [39]. The bottom-right inset of Fig. 6 shows the circuitry for a single channel of the PFG injector array – this is where the data is stored in analog form as charge on the floating gate $M_{FG}$. A more in-depth analysis of the operation of this particular PFG injector array, including linearity figure and stable injection rates has been reported in [33]. The source of a floating-gate pMOS transistor $M_{FG}$ is driven by a constant current source $I_{Ref}$ that is powered by either a piezoelectric transducer (during data-logging) or by some other energy source $V_{dda}$ (during programming or interrogation). As both of the energy sources are isolated by a diode, $V_{dda}$ supersedes the signal generated by the piezoelectric transducer. A full-bridge

**Fig. 5.** Working principle of Piezo-Floating-Gate technology.

**Fig. 6.** System architecture of the PFG sensor chipset with the schematics of select circuits shown in the inset.
rectifier (formed by four diodes) is used for extracting energy from the transducer and to drive the constant current source $I_{\text{Ref}}$. When the switch $S_{\text{Inj}}$ is open, the op-amp $A$ and floating-gate transistor $M_{\text{FG}}$ form a negative feedback configuration; the source current, $I_{\text{Ref}}$, is held constant which ensures that the source-to-gate voltage, $V_{SG}$, and the source-to-drain voltage, $V_{SD}$, remain constant during injection. Because all the terminal parameters of the floating gate transistor are held constant during the injection process, the injection current $I_{\text{Inj}}$ remains constant. Hence, the amount of charge injected onto the gate is linearly proportional to the duration for which the source current $I_{\text{Ref}}$ is activated and $S_{\text{Inj}}$ is open.

In the bottom-middle inset of Fig. 6 is presented a tunable voltage reference with startup circuitry, the tuning is achieved via an external resistor attached in series with one leg of the current mirror; thereby allowing us to manipulate the voltage at which the reference settles at. Within the bottom-left inset of Fig. 6 is the Pulse Encoder that generates a series of voltage pulses whose frequency will correspond to the observed voltage at $V_{\text{In}}$, which is a net shared among the buffered output of all channels.

IV. EXPERIMENTAL SETUP

The system on chip PFG prototype was fabricated in a 0.5 μm CMOS process. Fig. 7 shows the micrograph of the prototype and summarized in Table I are some of its measured specification. Fig. 8 displays the linear variation of floating-gate voltage with respect to the number of applied loading cycles. The voltage range and the injection rate (voltage reduction per cycle) are adjustable depending on the application and the desired number of cycles. They depend on different parameters such as the source current, input impedance, and levels of voltage generated by the piezoelectric transducer. These parameters have to be optimized for biomedical applications. However, their calibration is not addressed in this paper. The PFG sensor used in this work to monitor the bone healing progress and implant mechanical usage contains seven linear logging channels. The channels are programmed to trigger at different voltage thresholds. The higher is the generated voltage, the higher number of channels are logging. The minimum voltage level that is required to trigger the injection in each of the channels is shown in Fig. 9.

<table>
<thead>
<tr>
<th>Architecture Features for PFG Sensor</th>
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<tr>
<td>Process</td>
</tr>
<tr>
<td>Size</td>
</tr>
<tr>
<td>Minimum Energy (Self-powered Mode)</td>
</tr>
<tr>
<td>Power Dissipation (Read-out Mode)</td>
</tr>
<tr>
<td>Power Dissipation (Programming Mode)</td>
</tr>
<tr>
<td>Supply Voltage</td>
</tr>
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Fig. 7. The fabricated microchip under test, with a PFG injector array consisting of seven channels. The tuning capacitor and resistors are located off-chip.

Fig. 8. Linearity of injection with respect to loading cycles.

Fig. 9. Injection threshold for different sensor channels.
The phantom experimental setup for using the PFG sensors to monitor mechanical strain-levels during the bone healing process followed the setup presented in [31]. As described in section I, An unstable distal femur fracture was modeled by introducing a gap osteotomy on a synthetic femur replica. The gap osteotomy was then stabilized using a periarticular locking plate. The distal fixture was rigidly mounted to the base of a mechanical test system (MTS model Flextest 40 with series 370 load unit) using an epoxy layer that covers the distal tip of the plate. A compression load was applied to the femoral head center via a hinge joint such that the load vector intersects the femoral head and the epicondylar center.

Fig. 10. Experimental set up for strain measurements showing the implant, PFG sensor board and MTS setup.

Five measurement instruments were used to monitor the strain variation during testing. Two PZT-5A piezo ceramic discs (STEMINC-PIEZO, Part number: SMD12T06R412WL) were attached to the plate above and below the fracture. A piezo polymer coaxial cable (Measurement Specialties: 20 AWG Cable - Copolymer) was attached along the plate. A polyvinylidene fluoride (PVDF) film (model number DT2-Cable - Copolymer) was attached below to the plate. A compression load was applied to the femoral head center via a hinge joint such that the load vector intersects the femoral head and the epicondylar center.

Table II

<table>
<thead>
<tr>
<th>sensor</th>
<th>Dimensions (mm)</th>
<th>Elastic Modulus (GPa)</th>
<th>Capacitance (nF)</th>
<th>Electrical permittivity (x 10^9 F/m)</th>
<th>Piezoelectric Constant (d31) (x 10^{-12} m/V)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PZT-5A discs</td>
<td>ø12 x 0.6</td>
<td>76</td>
<td>2.9</td>
<td>16.38</td>
<td>190</td>
</tr>
<tr>
<td>PVDF Film</td>
<td>12 x 0.09 x 62</td>
<td>2</td>
<td>1.7</td>
<td>0.115</td>
<td>23</td>
</tr>
<tr>
<td>copolymer cable</td>
<td>ø 2.72 x 240</td>
<td>2.3</td>
<td>0.35</td>
<td>0.079</td>
<td>11</td>
</tr>
</tbody>
</table>

The sensor used in this set of experiments allows only a maximum number of 2,000 loading cycles. However, a bone healing period of four months is typically simulated by applying 200,000 loading cycles [41]. In order to ensure a higher testing period, and therefore allow full bone healing period simulation, the sensor’s impedance was adjusted by tuning the resistor on the PFG sensor board. Fig. 13 displays the channel injection rate for different resistance values. Results show that the sensor can be tuned to record up to 1.6 million loading cycles. However, for the current application...
the targeted number of cycles is around 200,000 cycles. Therefore to monitor a complete bone healing period, a resistor of 3.2 MΩ is installed on the sensor. The applied force was of 600 N amplitude cyclic at 2 Hz frequency. The materials used to simulate bone healing progress are presented in Fig. 13. Every 20,000 cycles the material used to fill the osteotomy gap is replaced by another material with a higher elastic modulus. The non-healing condition was experimentally modeled by applying 200,000 cycles without adding any material inside the osteotomy.

Due to their low mechanical to electrical coupling coefficients and non-uniform distribution of the strain along the implant, the PVDF film and copolymer cable generate a voltage that is less than 1 V. The piezo ceramic disc that is placed above the fracture line generates much lower voltage than the one below the fracture (2.5 V compared to 10.4 V) due to strain level difference. The difference is caused by the fact that the femur is subjected to both compression and bending due to load eccentricity. Fig. 14 displays the levels of voltage generated by each piezoelectric transducer, under 420 N load amplitude. Since PZT Disc 2 generates a voltage level that is sufficient to trigger the injection in all channels of the sensor, it was connected to the PFG sensor to monitor the bone healing progress.

Fig. 12. Properties of the materials used to emulate a slow bone-healing process.

Fig. 13. Response of the sensor for different values of the tuning resistor.

V. RESULTS AND DISCUSSIONS

A. Adequacy of the Sensor to Monitor Bone Healing Progress

Fig. 15 presents the relative variation of strain, PZT voltage and osteotomy compression, with respect to their initial values, during bone healing progress. The voltage generated by the piezoelectric transducer varies at the same rate as the implant strains and osteotomy compression. Therefore by recording the voltage, the sensor is able to monitor the strain variation continuously. During bone healing process, the induced strain levels decrease due to bones’ stiffening. Therefore the voltage generated by the attached piezoelectric sensor can be used as an indicative to the healing extent.

Fig. 15. Variation of strain, PZT voltage and osteotomy compression during bone healing progress.
B. Monitoring of a Complete Bone Healing Period

Fig. 16 presents the relative variation of strain and PZT voltage, with respect to their initial values, over the bone healing period. As shown previously in Fig. 15, the voltage generated by the piezoelectric transducer varies at the same rate as the implant strains. Impact ionized hot-electron injection process at the floating gate memory cell is activated only when the voltage is higher than the injection threshold. Therefore once the voltage drops below the injection threshold of a channel, it stops recording. Also the injection rate depends on the levels of voltage generated by the transducer.

Fig. 16. Variation of strain and PZT voltage during bone healing progress.

Fig. 17 displays the relative variation of the memory readings, with respect to its initial value. The dashed and continuous lines represent the response of non-healing and healing bones, respectively. The histogram represents the number of channels that are injecting into the floating gate memory cell. Results show that, as the bone is healing, the number of injecting channels as well as the injection rate is decreasing. A comparison between the two curves shows that when the bone heals, the recorded memory becomes invariant. Therefore, by reading the memory, it can be determined whether the bone regeneration is following the right path or revision surgery should be made. Fig. 17 presents the two extreme cases of bone healing: (a) condition when a union is successful; and (b) the condition when no bone regeneration has occurred. Note that in a typical healing process, the measured response will be a sensor response that will lie between the two curves presented in Fig. 17.

Fig. 17. Variation of the recorded memory value and the number of injecting channels during full bone healing period.

Fig. 18 shows the number of cycle at which each channel stops injecting. As can be seen, the seventh channel is the first channel to stop recording (at 100,000 cycles) because it has the highest voltage injection threshold. Then injecting channels shut off in a descending order. The first channel shut off means that the voltage generated by the PZT transducer is below the injection threshold and that the bone has healed. However, in the non-healing case, all channels are injecting at a constant rate until the memory saturates.

Fig. 18. Sensor channels cutoff cycles.

VI. Conclusion

This paper presented and demonstrated the feasibility of using PFG-based self-powered sensors to monitor the bone-healing process. The sensor is powered directly from strain variations of a fixation device and hence is continuously active without experiencing any loss of data. The outputs of the sensor are time-evolution curves and histograms that can be used to differentiate between different conditions of bone-healing. Our future work will involve clinical interpretation of PFG sensor data and will take into account the duration and variability in the bone-healing process. Decision of whether a bone is healing properly or not based on the sensor output can only be made by a clinician who has to take into account the nature of the fracture, age and weight of the patient. The presented results will be extended to construct bone healing curves as a function of the healing time. Wireless data retrieval will be incorporated within the sensor to ensure data retrieval using a hand-held ultrasonic device. Packaging and biocompatibility of PZT transducers will also be addressed in future work.
Different parameters of the sensor can be optimized in order to allow data logging for an extended period of time and to account for different quasi-physiological load amplitude depending on the patient’s weight. This work reported results from a single PFG sensor located at the fracture site. However, the fracture site is different for different trauma and is also dependent on the patient’s size. Therefore, in a practical deployment, multiple sensors will be integrated along the fixation device to ensure that at least one sensor is always located at the fracture site. Normal service loads will be larger than the loads studied in this paper (420 and 600 N), therefore, the induced strain will be sufficient to self-power an array of PFG sensors.

ACKNOWLEDGEMENT
The authors would like to thank Dr. Aaron Purdue from University of Michigan and Dr. Hallie P. Brinkerhuff from Zimmer-Biomet for their valuable comments and discussions regarding the progression of bone-healing and the integration of the PFG sensors onto the fixation-device. This material is based upon work supported in part by the National Science Foundation STTR Phase I grant 1417044 (Sub-contract through Piezoxics LLC) and Graduate Research Fellowship Program under Grant No. DGE-0802267 and DGE-1143954. S. Chakrabarty and N. Lajnef are co-founders of Piezoxics LLC and have financial interests in the company. Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation.

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