Implantable Autonomous Device for Wireless Force Measurement in Total Knee Prosthesis

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Heath maintenance is one of the most challenging objectives of science and technology. Nowadays, with the rapid progress in the field of biomedical engineering, implantable medical sensors and devices are widely used for prognosis, diagnosis and treatment [1] without interfering in a patient's normal life activities. These implantable devices include cochlear implants, pacemakers, nerve stimulators, heart failure monitoring devices, smart prostheses and many others, which perform real-time monitoring and control of certain functional body operations.

However, inside the human body, power autonomy is a main issue, as implanted batteries are not feasible for long term use of any implantable devices. Though recently, batteries have improved energy capabilities as compared to those in the past. For instance, lithium-ion batteries have attained a greater level of energy density (up to 0.2 Wh/g) [2], but their repetitive usage requires their replacement. Hence, in order to omit external power sources, a viable solution is to implement an energy-harvesting system (self-powered system) which can take energy from the human body and convert it into electrical energy [3]. Biomedical implantable devices driven by power harvesting systems possess longer lifespans and provide more safety and comfort. Thus, researchers made extensive efforts to develop different strategies and methods to harvest energy from different sources for implantable biomedical devices.

It has been proved that the human body can also act as one of the best energy reservoirs for harvesting energy [4], which includes biochemical, thermal, and kinetic energy. Biochemical energy can be obtained from glucose and oxygen present in blood. Devices that use biochemical energy include implantable biofuel cells that can harvest energy by using blood glucose as a reactant [5]. Another available source of energy is thermal energy, which could be used to power implanted pacemakers [6], and hence substituting for traditional batteries. Furthermore, movement of the human body also acts as a great source of kinetic energy which can generate enough power for the implanted devices [7]. In [8], it has been shown that power can be extracted (μW to mW) from the movement of head and trunk of the body during running or walking. Moreover, in several other related works, human kinetic energy has been used to harvest energy for medical implantable devices [9].

Kinetic microgenerators convert kinetic energy into electrical energy and there are three types depending on energy transduction methods i.e., piezoelectric, electrostatic and electromagnetic generators [10]-[12]. Piezoelectric generators are not suitable for medical implants because of their large size and massive motion [13]. On the other hand, electrostatic generators are not appropriate for *in-vivo* application because of their size constraints and low generated output power limits [11].

In the presented research, we have adopted an electromagnetic energy transduction mechanism to design a self-powered force measuring autonomous device for total knee prosthesis (TKP), which is required after Total Knee Arthroplasty (TKA). Normally, the most affected part of TKP is the polyethylene insert due to tibiofemoral forces acting on this component [14]. Thus, there is a need for such a medical device that can measure forces acting on the knee implant and provide monitoring of the knee prosthesis. Hence, we especially focused on designing a self-powered measurement device that can be implanted inside the human body, in particular inside a prosthesis where the monitoring of the knee joint and the limb movement is important for a correct use of the prosthesis and therefore for improved life quality. Measuring inside the human body often represents a challenge, both due to the impossibility of using batteries and for the design constraints related to compatibility and reduced dimensions. Several implantable systems using Tekscan sensing systems, fiber Bragg gratings or strain gauges have been designed for monitoring implant conditions [15]-[23]. However, every system uses either an external power source or a telemetric system to power the device.

This paper presents a new proposal for the measurement of the force acting on the knee by means of a device powered directly by the movement of the knee, and hence no external power source is required. The design choices and considerations reported can help designers solve some of the recurring problems in the literature concerning measuring devices implantable within the human body. Previously, in [24] we

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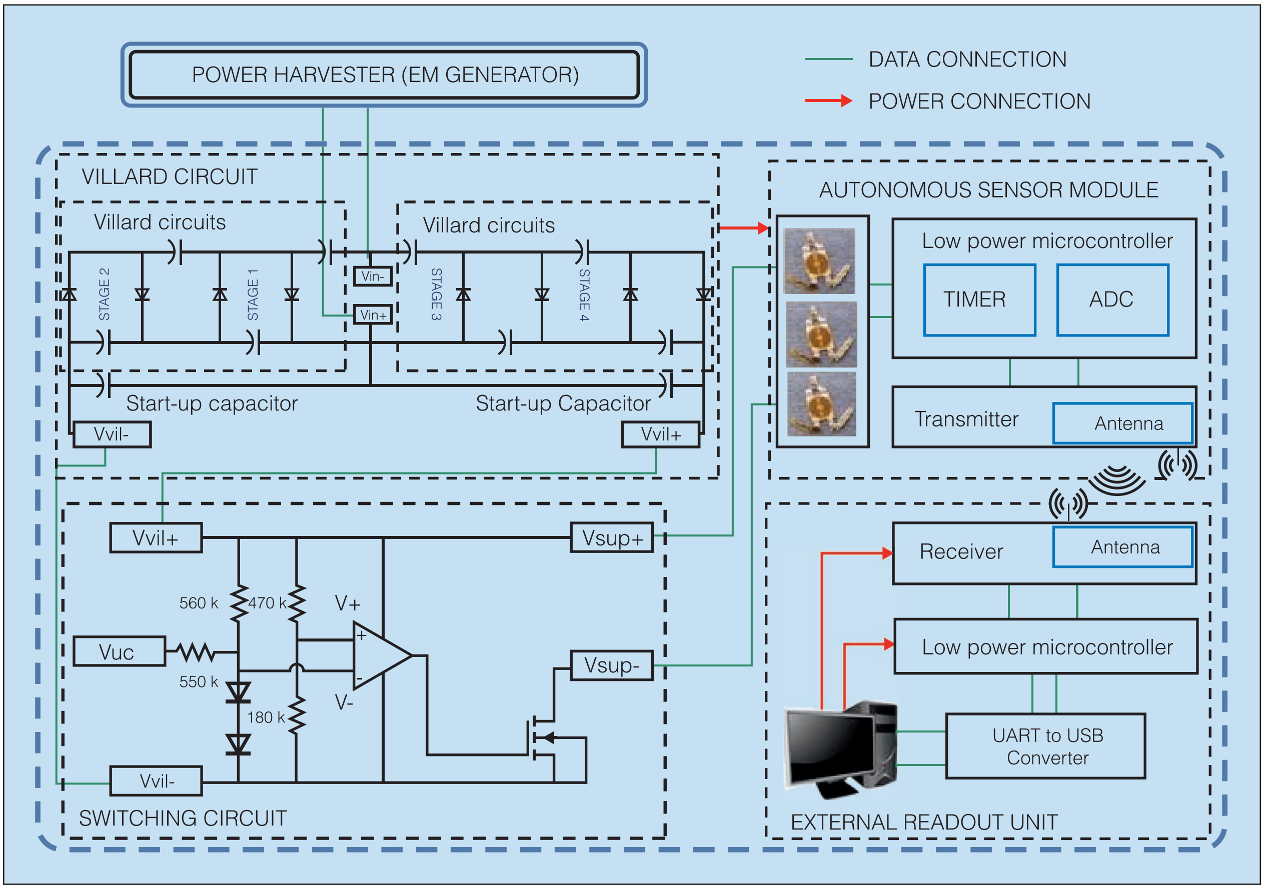

Fig. 1. Schematic diagram of overall implemented system.

presented the design (only implanted unit) and testing of a force measuring device for knee implants using the telemetric technique for data transmission. Afterwards, the telemetric module was replaced by a power harvesting system, and initial experimental results of the power harvesting module were reported in [25]. Preliminary results on a new power harvesting module are described in [26], and in this paper the complete device design (implanted unit and external readout unit) along with power harvesting behavior at various frequency levels is explained.

The first section highlights the device design. The next section describes the experimental setup used for working and testing the device. Experimental results of the power harvesting unit, data transmission and other electronic signals are reported subsequently, and the final section provides conclusions and future work.

System Description

The proposed device is completely integrated into the total knee prosthesis. The schematic representation of the overall device is presented in Fig. 1. The implanted electronic board consists of a power harvesting module (Villard circuit and switching circuit) and an autonomous sensor module (magnetoresistive force sensors, signal conditioning circuit, microcontroller and transmitter). The power harvester is an electromagnetic generator that acts as a knee simulator to reproduce the knee movement and to test the implantable device performance. The power harvester converts mechanical energy into electrical energy based on an electromagnetic generator mechanism. It is composed of 12 NdFeB magnets inside each condyle of the femoral component along with an inductor placed in the polyethylene insert. The movement of the femoral component allows the movement of magnets relative to a static coil, which causes magnetic flux variation, and hence electric voltage is induced. The detailed mechanism of electromagnetic generator used is described in [27]. The power harvester is connected to the implanted electronic board placed inside the insert. During walking, the system is able to perform real-time monitoring of the femoral force acting on the total knee prosthesis. The collected data are transmitted to an external readout unit that decodes the received data.

Implanted Electronic Board

A power harvesting module composed of a Villard circuit and a switching circuit has been designed to automatically power the electronic circuit implanted within the polyethylene insert by the harvested energy from knee movement. This harvested energy is converted into amplified voltage and then used to power the microcontroller and the electronic circuit of the implantable device, hence eliminating the need for batteries or any other external power sources. The harvested energy is stored in capacitors as they can be charged quickly and can last

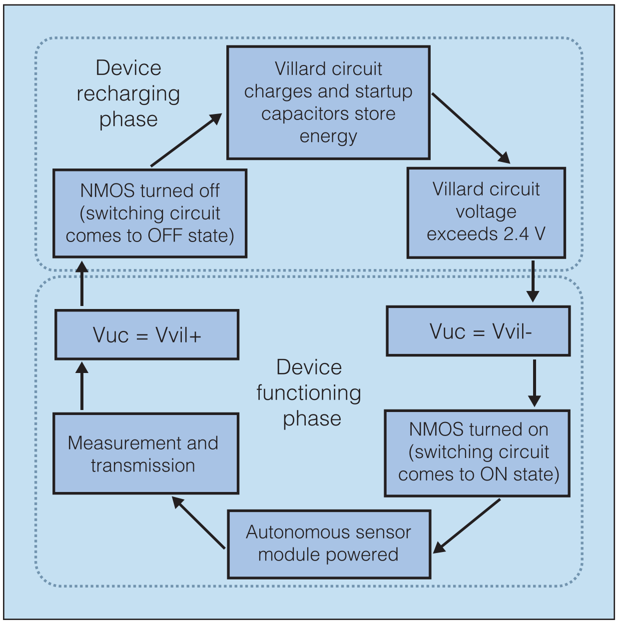

Fig. 2. Working mechanism of power harvesting module (Villard circuit and switching circuit).

for millions of charge / discharge cycles without losing energy storage capacity. Additionally, the design of the overall device has to be compact and cost effective; therefore, we choose capacitors that have higher chagrining/discharging capability, low cost and small size.

In this design, a four stages Villard circuit has been chosen as a voltage multiplier topology and has been prioritized over other voltage doubler methodologies, as it is more efficient for power harvesting applications [28]-[30]. The Villard circuit executes an ac/dc conversion of the input signal that comprises a tantalum capacitor (solid SMD - Voltage Rating dc: 4 Vdc, Tolerance: 20%, Discharge Current Limit: 27.2 µ A) and Schottky diodes (RB551V 30 - Threshold Voltage: 150 mV, Current Value: 1 mA). The implanted electronic board needs approximately 2.2 V for processing and transmission of data; therefore, considering an induced voltage of about 0.6 V at 1 Hz, a four stages Villard circuit has been chosen. It has been divided into two Villard circuits, each with two stages to utilize both positive and negative cycles of the ac harvested voltage. Hence, one Villard circuit will perform amplification on a positive input cycle and the other will utilize a negative input cycle and thus, will collectively contribute in amplifying the voltage without wasting any input cycle.

The Villard circuit is connected to switch circuit (Fig. 2) via two start-up capacitors. The switch circuit contains two fast switching diodes (1N4148) and the LT6003 comparator (by Linear Technology). The circuit is grounded via NMOS that is driven from a comparator output, which is powered by Villard outputs (Vvil+ and Vvil-).

The working mechanism of the power harvesting module is shown in Fig. 2. Initially, the switch circuit is OFF and start-up capacitors are not connected to the electronic circuit because the NMOS transistor (Si2342DS) is in turned OFF state. In this condition, start-up capacitors will store the energy harvested by the Villard circuit up to the switching ON level. Thus, when the Villard voltage across the start-up capacitor surpasses the specific value of about 2.4 V, the comparator will switch ON the transistor and start-up capacitors will get connected to the sensors, signal conditioning circuit and transmission circuit. After connecting, start-up capacitors will discharge across the electronic circuits and hence provide energy to the implantable device for performing required operations. In this phase, the microcontroller makes Vuc = Vvil- and hence keeps the transistor turned ON which will ensure the power supply to the electronic circuits until the measurement and transmission of data has been executed. Once the operation is completed, the microcontroller will automatically disengage the power supply by imposing Vuc = Vvil+. This will initiate the charging of start-up capacitors through the Villard circuit and the cycle continues. Thus, in this way the microcontroller controls the activation of the sensor system for data transmission only when needed, thereby reducing overall power consumption by avoiding dead time.

The forces applied on the ultra high molecular weight polyethylene (UHMWPE) insert are transduced by two magnetoresistive sensors. The location of magnetoresistive sensors were chosen according to the human knee implant shape. Two of them were placed near the two contact areas of the femoral condyles, and the third one was positioned in between the two sensors, equidistant from the two femoral condyles. Thus, when a force is exerted on the femoral part of knee implant, it is transferred to the UHMWPE insert and causes deformation in the insert. This deformation causes the change in distance between the permanent magnet and magnetoresistor sensor, which in turn modifies the magnetic field around them. Hence, resistance variation is produced on the force sensor output due to applied force on the femoral component. The magnets are composed of Sm_2Co_{17} (samarium–cobalt magnet) and they have 3 mm length with 4 mm diameter.

The temperature change can also cause variation in the magnetoresistor output and at normal walking of around 45 min the body temperature rises by 3 °C [18]. Therefore, a third dummy magnetoresistor (temperature sensor) has been placed in between the two magnetoresistors in a Wheatstone bridge configuration to evaluate and compensate for the effect of temperature on magnetoresistor resistance. The experimental results presented in [24] show that the effect of temperature has been restrained by implementing a mathematical equation via microcontroller. Furthermore, high resistances were used to have low current branch in the Wheatstone bridge to limit the different voltage variation with temperature variation. The implemented conditioning circuit is shown in Fig. 3.

As the sensor output data has to be transmitted wirelessly to the external readout unit, therefore, an appropriate Manchester coding and amplitude-shift keying (ASK) modulation has been adopted. In ASK modulation, the carrier signal amplitude corresponds to binary logic 1s and 0s, which represents modulated signal with and without carrier, respectively. Here ASK modulation has been preferred because, when a signal is

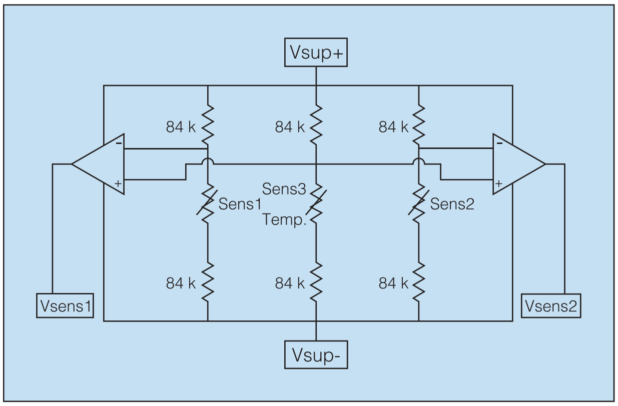

Fig. 3. Wheatstone configuration of force sensors and signal conditioning circuit.

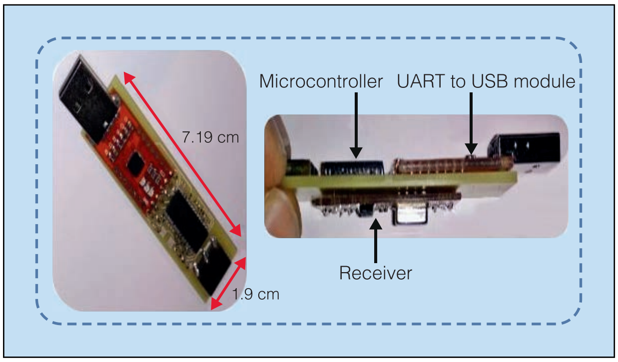

Fig. 4. Hardware implementation of external readout unit.

transmitted with "0 logic," it radiates a very weak signal which results in less power consumption by the device. On the other hand, Manchester coding is used due to its built-in synchronization, which optimizes the output reliability and reduces the error rate. Moreover, the working frequency chosen for transmitting data is 433 MHz since lower frequency propagation channels result in much lower signal attenuation as compared to higher frequency [31]. Similar frequency of 418 MHz has been used in [32] for wireless transmission of *in vivo* measured tibiofemoral forces. For medical implant devices, 402–405 MHz is an optimum working frequency range [33], but according to J. Gemio *et al.*, results of the 433 MHz band can also be considered valid for medical implant communication system (MICS) devices [34].

The transmitter on the implantable board has low energy consumption (5.5 mA) because the minimum energy available to the implant does not allow complex processing on the transmitting data. The adopted transmitter is a QAM-TX1 module produced by QUASAR, which enables ASK modulation with an operating frequency of 433 MHz. It is also compatible with TTL level and can work with a supply voltage from 1.5 V to 5 V. The antenna chosen is an ANT-433-μSP produced by Antenna Factor by Linx with minimal size of 12.7 mm x 9.14 mm.

External Readout Unit

Once the transmission is initiated by the implantable device, the external readout unit receives the data. The readout unit mainly encompasses a 433 MHz receiver, antenna, microcontroller and UART to USB module. The antenna is an ANT-433-μSP produced by Antenna Factor by Linx, the same as in the implanted circuit. Instead the receiver is a QAM-RX4 module produced by QUASAR which offers high sensitivity (-106 dBm), low current consumption (4.7 mA), typical supply voltage of 5 V (as USB power supply) and stable operating frequency. The various modules used in the readout unit have been distributed on three levels to create a prototype with a dimension of a classic flash drive (Fig. 4). At the bottom side there is the receiver QAM-RX1, and at the first level of the upper side there is the PCB that contains the PIC 18F2455 and the antenna Ant-433-uSP, whereas at the second level of the upper side the UART to USB module (chip 2102) has been placed. Hence, the total dimension of the readout unit is roughly 2 cm x 7.2 cm and it is powered using the voltage provided from computer USB port. The receiver receives and demodulates the data from the 433 MHz carrier signal and then demodulated data is decoded by the microcontroller. An easy microcontroller-PC communication is done by the UART to USB module, which allows reading the module on a PC as a virtual COM port.

The Windows application has been developed to display data and will be able to interface with this module as a simple communication on a Virtual COM Port. The development environment used for the Windows application is 'Qt,' a cross-platform application framework that is widely used for developing application software and can be run on various software and hardware platforms with little or no change in the underlying codebase. The Windows application is shown in Fig. 5 and contains following features:

- Selection of different Virtual COM Ports
- Connection and disconnection of the Virtual COM Ports
- Displays address of the total knee prosthesis (the address has the hexadecimal value '0xAB')
- Displays current value of tibia-femoral force measured by sensors (10-bit ADC microcontroller, so values are from 0 to 1023)

Apart from the designed PC-based custom program, any portable system (laptop, smartphone, tablet) equipped with

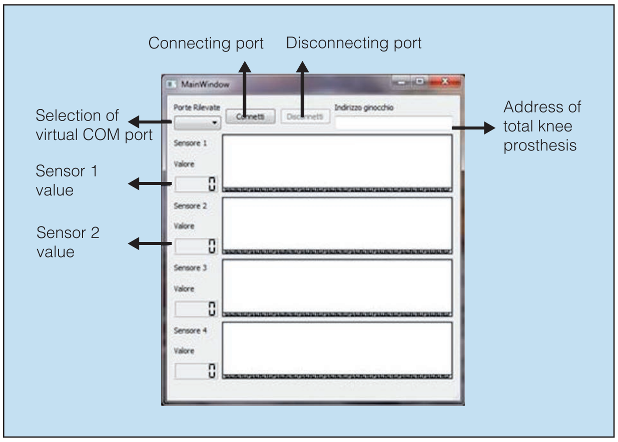

Fig. 5. Windows application for display of measured sensor data.

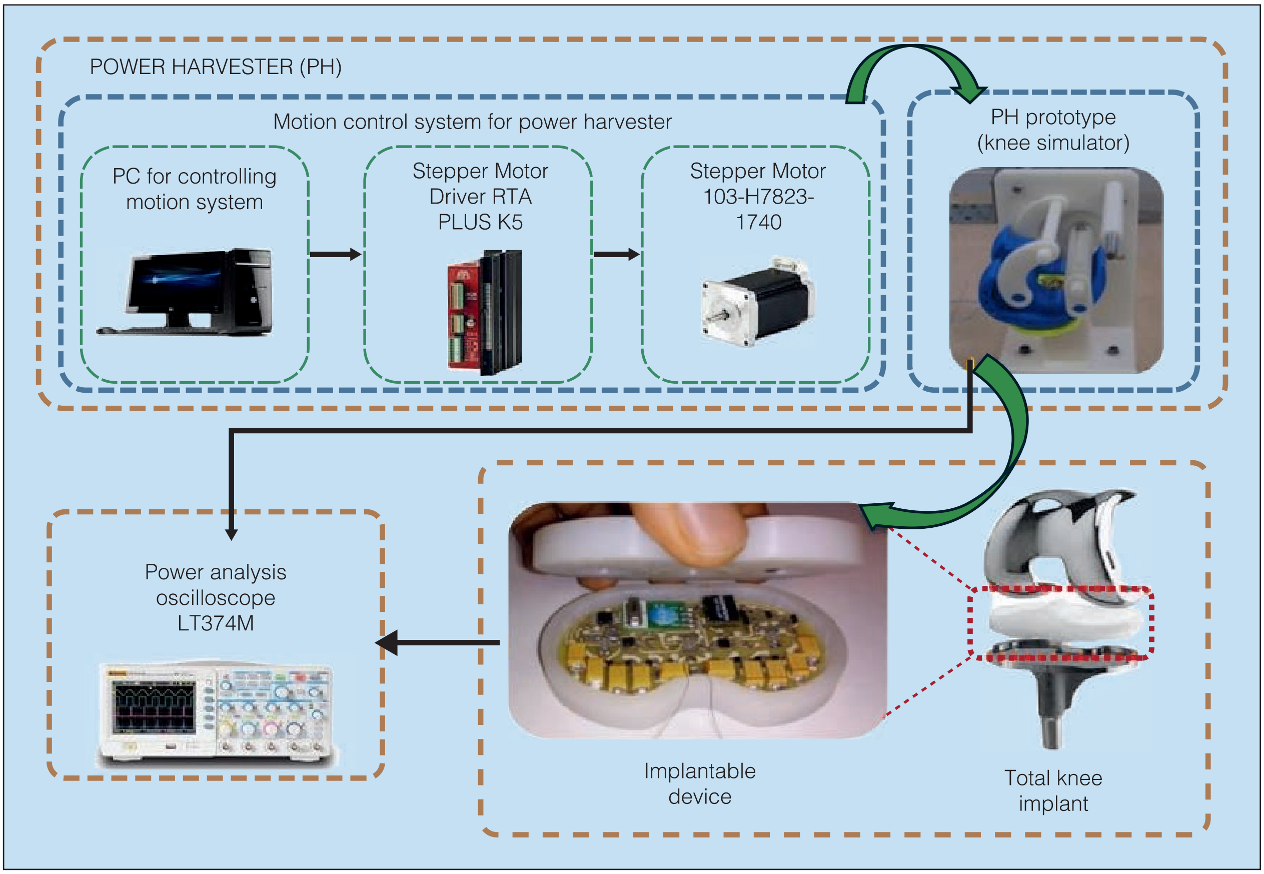

Fig. 6. Experimental setup for device testing.

our proposed reading module could also be adopted as a reading system. It is only required to develop an application/program able to receive the data and to elaborate the measurements for real-time monitoring.

Experimental Setup

To validate and test the performance of the fabricated device (power harvesting characteristic, data transmission and other electronic signal responses), an experimental setup has been installed (Fig. 6) which mainly comprises a power harvester (knee simulator and its motion control system), implanted device and digital oscilloscope. In order to simulate knee movement, a motion control system and a knee simulator have been used. The designed electromagnetic generator (EMG) based knee simulator has been used as "power harvester" and has the capability to simulate knee movements at several walking frequencies. The detailed design and working of power harvester prototype (knee simulator) was presented in [27]. The motion control system used for actuating the power harvester (PH) prototype is in open loop state, which consists of a PC-based motion controller, programmable drive RTA PLUS K5 and Sanyo Denki stepper motor (model: 103–H7823–1740), with acceleration of 35700 rad·s-2 along step angle 1.8°±0.09°. The knee simulator is then connected to the implantable device, which acts as a power input for the power harvesting module of device (Villard circuit input). Finally, the device and simulator response is visualized and analyzed via digital oscilloscope LT374M.

Experimental Working Conditions Analysis

A functioning analysis of the device was performed under different working conditions. First, the power harvesting feature was analyzed, aiming to identify the charging time interval between two consecutive measurements with different walking frequencies. Then, the force measurement and overall implantable circuit board was tested and verified.

Power Harvesting Working Conditions

The implanted electronic board has an average current consumption of 5 mA during measurement and transmission activities (active mode) with an average operating voltage of 2.25 V, and around 23 ms is required to perform all of the activities in active mode. In addition, 260 μJ of energy is needed by the device to perform measurements. Therefore, start-up capacitors of 330 μF are selected based on this required energy. After selection of start-up capacitance, several experiments were performed to select optimized values of capacitance for the Villard circuit. Initially, tests have been performed with walking frequency of 1 Hz (1 step/sec) as it is equivalent to a normal walking speed, and the knee simulator has been used to simulate the desired walking motion. The experimental

Table 1 – Device response of optimized case at various walking frequencies		
Walking Frequency (Hz)	Initial Charging Time (s)	Average Charging Time for Next Transmission (s)
1.0	9.6	1.8
0.9	10.8	2.2
0.8	13.2	2.6
0.7	17.0	4.1
0.6	20.4	6.8
0.5	34.0	8.5

results for energy calculation and capacitance selection for optimized power harvesting module were presented in [26]. Now the detailed analysis of the optimized case has been discussed with a walking frequency equal and less than 1 Hz. For experimental analysis, frequencies less than 1 Hz were considered because patients with total knee replacement are normally advised by the doctor to keep a low walking speed few months after surgery. From Table 1, it is clear that the charging time of capacitors increases with a decrease in frequency. The initial charging time corresponds to the number of walking steps, depending on the selected frequency. For instance, at the walking frequency of 1.0 Hz (1 step/s), an initial charging time of 9.6 s corresponds to 10 walking steps, whereas at 0.5 Hz (half step/s) the charging time of 34 s is required for every next recharge and measurement. The mechanism and time period for charging and discharging of the Villard circuit can be observed in Fig. 7. The device response at frequencies lower than 1 Hz is shown in Table 1.

Furthermore, threshold-walking frequency has been found at 0.5 Hz, as below this frequency no data transmission was carried out due to low available energy.

Force Measurement

The overall system was validated via an experimental setup composed by an autonomous sensor system (polyethylene insert and external readout unit), Instron 8051, Fluke multimeter, Lecroy LT374M oscilloscope and operating PC. The load has been applied by Instron machine on the femoral component of the total knee prosthesis that causes the change in resistance of magnetoresistors located inside the polyethylene insert. Depending on resistance variation, the device calculates the amount of force applied on the knee joint and sends it wirelessly to the external readout unit. The oscilloscope is used to monitor the uninterrupted transmission of signals. An analysis of the calibration procedure and the force data measured by magnetoresistors was presented in [24].

In Fig. 8, the forces measured by the Instron are compared with the forces calculated by the autonomous system (R_Right: Right magnetoresistive sensor and R_Left: Left magnetoresistive sensor) within a wide range of 0–3 kN. The measurement data obtained by the autonomous sensors have variability more evident for R_left. The mean difference between the force value applied by Instron and the calculated value by the autonomous system is about 15%. This variability could be due to hysteresis effects, power fluctuation and external noise. In the future, the device performance is expected to improve by compensating for these external factors. However, the force data, even with a high variability, demonstrates that the prosthesis and in particular the polyethylene insert, has undergone high stress, allowing the subject to correct wrong behaviors.

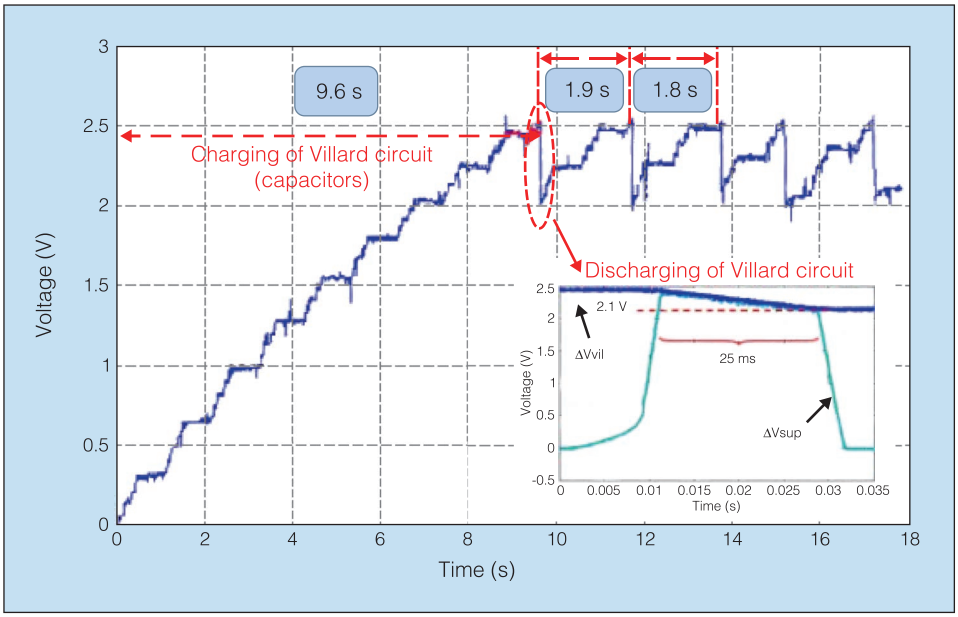

Fig. 7. Experimental results of power harvesting module at walking speed 1 Hz.

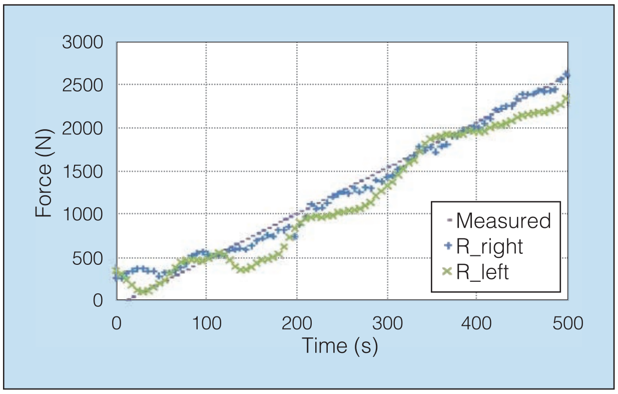

Fig. 8. Comparison of force measured by autonomous sensor and force measured by Instron.

Overall Testing of Implantable Circuit Board Signals

Signals from the power management circuit, microcontroller and other electronic circuits have been analyzed to evaluate the working behavior of the overall device (Fig. 9). It can be seen that when the microcontroller is powered, it imposes the switch-ON signal (Digital 0) (red) to bring the power harvesting module into the discharging phase (blue) and power the electronic circuit of the device (magenta). Hence, when the microcontroller is powered, at that instance the two instrumentation amplifiers (the green curve represents one of them) generate output voltage (sensor output) and, in the current case, stabilize to 0 V (because the system is without any load). Once the signal stabilizes, ADC data acquisition occurs (light blue interval), and finally data are transmitted to the transmitter block in a serial fashion (black). The data transmission is done in serial manner instead of saving the data in the non-volatile memory of the microcontroller and making a single transmission each step if possible, because, the aim is to provide continuous real time monitoring of the prosthetic knee implant.

Once the transmission is done, a switch-OFF pulse (digital 1) is sent by the microcontroller (red) to power OFF the circuit and bring the power harvesting module into the charging phase. In addition, it is noted that the voltage produced by the power harvesting circuit is decreasing (blue) while performing necessary device operations (23 ms) because the energy provided to the device is in continuous discharging of capacitors. Furthermore, the device will be switched ON only for 25 ms and then switched OFF automatically until the microcontroller sends another switch-on pulse. This ON/OFF mechanism makes the device more power effective.

Conclusion and Future Work

In this paper, the design and test of a self-powered force measuring device has been presented. This system allows continuous monitoring of a knee prosthesis after total knee arthroplasty. The complete device has been tested to validate the performance of the power harvesting system and efficient wireless transmission of measured force. The implemented

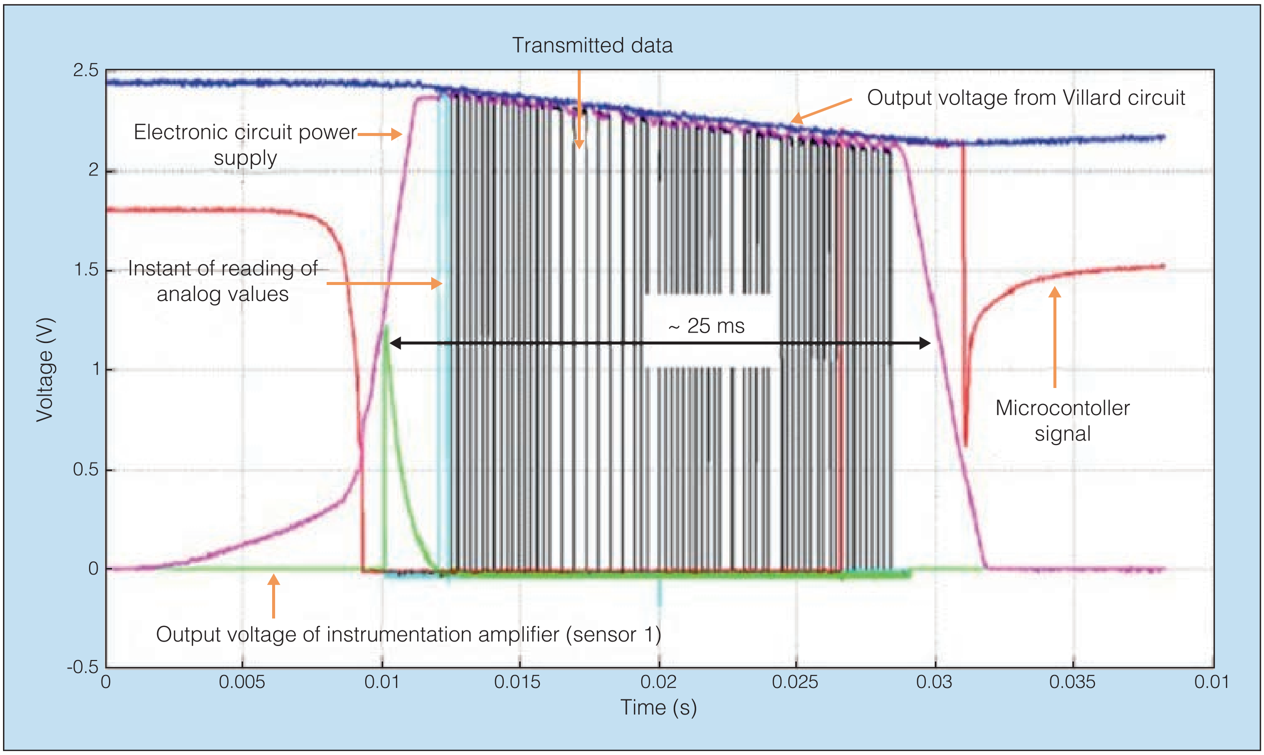

Fig. 9. Voltages measurements of "implanted circuit." Blue: Output voltage from the Villard circuit ($V_{outvillard+}$ - $V_{outvillard-}$) Magenta: Electronic circuit power supply (V_{sup+} - V_{sup-}) Red: Microcontroller signal. Green: Output voltage of instrumentation amplifier (sensor 1). Light blue: Instant of reading of analog values. Black: Transmitter signal (Data).

power harvesting module eliminates the need for batteries or any external power source and will derive energy from human walking. Moreover, the measured force is also transmitted to an external readout unit wirelessly, which will further increase comfort and ease for the patients. The time needed for reading, processing, encoding, and transmitting data is minimized to 25 ms, which decreases the power consumption and makes the overall device more power effective. The experimental tests are performed to analyze the behavior of the power harvesting system of the device at a frequency range of 1 Hz to 0.5 Hz (with a decrement of 0.1 Hz). The results show that walking frequency is inversely proportional to the charging time of the Villard circuit capacitors i.e., charging time increases as the walking frequency decreases. Thus, at 1 Hz the device takes a shorter time (9.6 s) and fewer walking steps (10 steps) to charge and perform the first measurement. As the frequency decreases the recharging time of device increases, and at 0.5 Hz it requires the maximum steps (17 steps) and longest charging time (34 s). In addition, the threshold frequency at which energy can be harvested from patients' normal walking is found to be 0.5 Hz (half step per second), and below this frequency, no measured data can be transmitted externally. Moreover, the force measurement results of an implantable autonomous device are quite promising. However, in the future, further improvements will be made to increase the accuracy of the device to measure tibiofemoral forces along with further reduction in energy consumption and transmission time. Additionally, further experiments will also be performed *in-vitro* with total knee implants to check the device's response in a more real scenario. Hence, this autonomous force measuring sensor is an innovative step towards totally autonomous measurement devices implanted inside the human body.

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