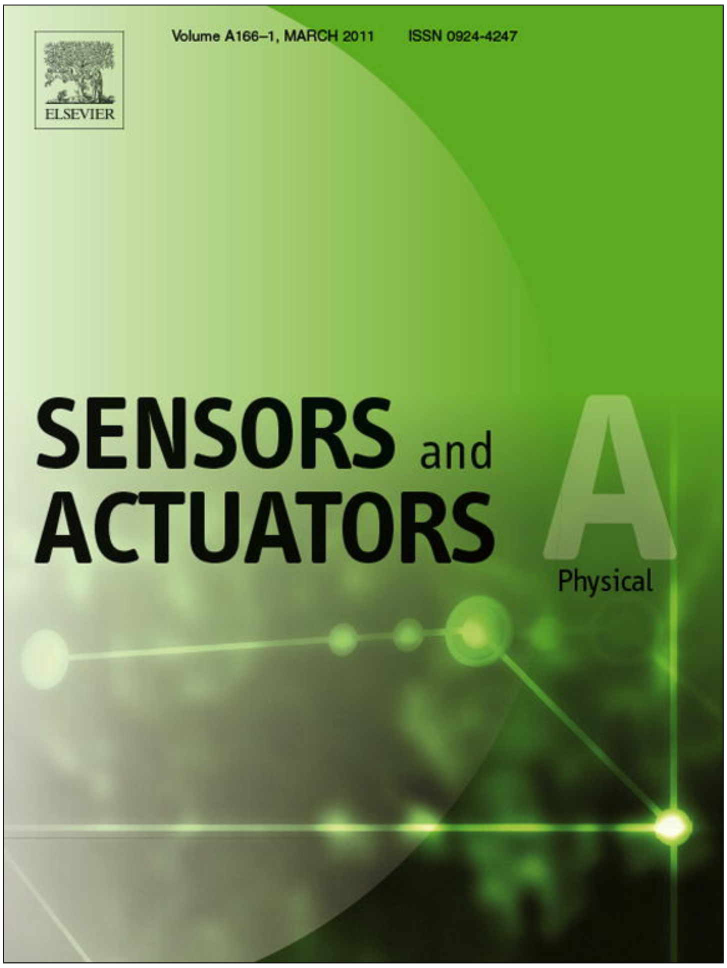
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Design and test of an autonomous sensor for force measurements in human knee implants

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A B S T R A C T

In vivo monitoring of human knee implants after total arthroplasty increases information concerning articular motion and loading conditions. The autonomous sensor proposed carries out force measurements in a protected environment and wirelessly transmits data directly from the inside of the implant to an external readout unit. The autonomous sensor is fully contained in the polyethylene insert. Batteries are completely eliminated; the system gathers energy from an externally applied magnetic field using a miniature coil inside the implant. The data generated from this device will provide data for new designs, techniques and implementations. The forces transmitted across the knee joint during normal human activities such as walking, running or climbing can be directly measured. Furthermore, the device can be used to improve design, refine surgical instrumentation, guide post-operative physical therapy and detect human activities that can overload the implant.

1. Introduction

Autonomous sensors are devices that autonomously execute measurement functions. Since they are unwired from the acquisition unit they have both independent power source and ability to measure and transmit data. They can be used in measurement applications inside the human body avoiding the risk of infections or skin damage since they do not require transcutaneous wires.

In many medicine fields measurement operations are required. In orthopedic science, for example, during surgical operation in total knee arthroplasty, measurement devices of tibiofemoral contact stress give precise knowledge of articular motion behavior and loading conditions; human joints are subject to a wide range of loads during daily activities. Much effort has been done to study the mechanical behavior of the human knee joint and quantify the forces transmitted between the femur and tibia. Strain gauges or thin-film pressure transducers attached to implants or directly to the bone and connected by wires to an external measuring system have been presented in [1–7]. In [1], a customized transducer was developed to measure the dynamic tibiofemoral force and pressure centre after total knee arthroplasty. The sensor consists of four uniaxial load cells. The device is used for in vitro testing.

Thin-film pressure transducers such as k-Scan are examples of cabled solutions. The k-Scan system consists of a thin-film (0.1 mm) electronic pressure transducer; the sensor usually has two sensing arrays, each with several sensing elements. In [2], an electronic sensor based on k-Scan system was used to detect the tibiofemoral contact and to measure the peak and the mean stress under compressive loads. In [3], a comparison of k-Scan sensor and Fuji film suggests that the k-Scan provides an easier method with more accurate measurement. The k-Scan was extensively studied in [4] focusing the difficult in the practical application. As reported in [5], these sensors have to be introduced between the tibial and femoral articulating surfaces, so they can alter the natural contact topology. In [5], fiber Bragg gratings (FBGs) were chosen as a sensing medium due to their flexibility, sensing and multiplexing capability. These types of fibers have a grating built in the core of the optical fiber, where the period of the grating changes with applied perturbations and is enclosed in the reflected or transmitted wavelength. Different methods to predict the polyethylene wear are reported in the literature. In [6], an index to predict the wear of the implant

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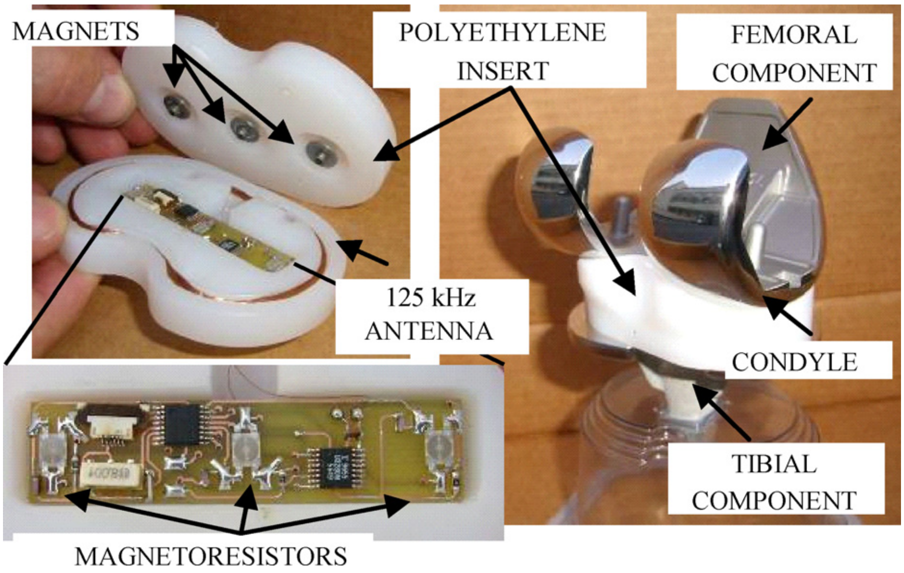

Fig. 1. Schematic configuration of a typical human knee implant and images of the autonomous sensor.

is defined as the product between deformation and sliding velocity. Some tests have been conducted over different implants simulating the effect of the knee joint with the aim of evaluating the relative wear; a comparative table has been obtained. In [7], the authors report the results of pressure measurements on the tibial plateau of cadaveric knees under dynamic physiological loads. The pressure values and contact areas were measured using a k-Scan sensor.

Fluoroscopy is another technique used to analyze postoperative kinematics in total knee arthoplastic and permits a contactless measurement. In [8], the pressure data obtained with an intra-operative sensing device is compared with the postoperative fluoroscopic results. Another contactless device, used to provide feedback on knee flexion angle for injury prevention that is used for monitoring the kinematics of total knee prosthesis, is reported in [9]. The device uses an Optotrak motion analysis system which can track and measure the 3D movements of six infrared emitting diodes placed on the knee. The results give a precise analysis of the movement during the different knee movements. In [10], the authors propose a completely new load-monitoring concept, which consists of a passive load sensor and an associated external ultrasound-based read-out unit. The measurement principle is based on the transformation of an external force in a varying amount of fluid in a microchannel integrated in the sensor. An ultrasound readout method is described to determine the amount of fluid in the microchannel.

The force acting on the human skeletal structure can also be measured in vivo by means of instrumented knee implants. In the literature, examples of autonomous sensors powered inductively are reported in [11–19]. The items describe two research activities: the first, from [11] to [14] concerns an integrated measurement system having two antennas, one for power harvesting and the other for transmission; the sensor is applied to the stem of the metal structure that was completely redesigned. In [11,12] a hip endoprothesis was instrumented with sensors to measure the shoulder joint forces and the temperature distribution of the implant. The stem contains a coil for the inductive power supply of two telemetric units. The power consumption of one telemetric unit is about 10 mW. The authors propose a similar instrumented implant for in vivo measurement of tibial tray [13] and for vertebral body replacement [14]. The second work by D'Lima et al., reported in [15–17] presents a measurement system applied to the prosthetic knee with similar characteristics to those of previous authors [11–14]. The tibial insert is made of two metal parts properly designed for inclusion of strain gauges for measuring the deformations of the tibial insert. In addition, this device has two antennas. In [16–19], the characterization and several results both in vivo and in vitro are reported.

As previously reported, a lot of different paper testifies the great interest towards force measurements in human knee implants. In this article, an autonomous sensor is proposed as a force measurement device as an alternative system from the previous version. It executes autonomously the force measurements and wirelessly transmits the data directly to an external readout unit. The whole measuring system is fully contained in the polyethylene insert, avoiding in this way the biocompatibility problems and modifications of shape dimensions of the traditional implant as required by other similar application [11–19]. In the autonomous sensor proposed, the batteries are eliminated. By using a coil within the implant, the autonomous sensor gathers energy from an externally applied magnetic field. The same coil also communicates avoiding the necessity of another antenna. In [20], a previous version of the autonomous sensor describes preliminary results demonstrating the functioning of measuring, data saving and wireless communication. In this article, an improved version of the autonomous sensor is described together with a complete experimental testing.

2. The autonomous sensor system

Fig. 1 shows on the right side a human knee implant that is composed by UHMWPE (Ultra High Molecular Weight Polyethylene) insert, a femoral component and a tibial component. On the left side, Fig. 1 reports above an inner section of the polyethylene insert, where the autonomous sensor is hosted highlighting the magnets and the antenna, while on the left and on the downside the circuit board with the magnetoresistors are shown. The autonomous sensor system is composed by three magnetoresistive force transducers, low-power electronics for conditioning and RF communication, and energy harvesting capabilities. The electronics, including the sensing elements and the antenna, are fully contained within the polyethylene insert, which can be hermetically sealed using laser welding techniques.

The magnetoresistive force transducer consists of a magnetoresistor and a permanent magnet. The magnetoresistor is a Sn-doped single crystal film InSb deposited by thin film technology over on alumina substrate (Ashai Kasei Corporation, Japan). The permanent magnets are made of Sm_2Co_{17} (samarium–cobalt magnet)

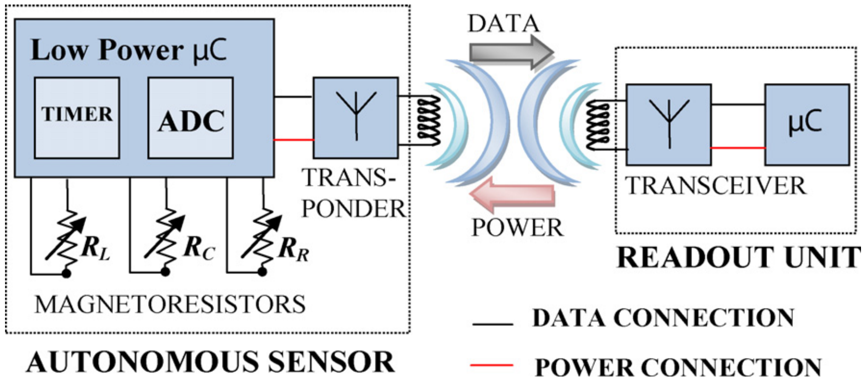

Fig. 2. Block diagram of autonomous sensor system and readout unit.

diameter 4 mm and length 3 mm. Two strips of material having high relative magnetic permeability (µr) (Ni–Fe–Mo alloy) direct the magnetic field along a designed path to control the magnetic field amplitude and avoid possible external noises. When a force is applied on the femoral component, the force is transmitted to the polyethylene insert, generating a deformation on the polyethylene insert. This deformation changes the distance between the magnetoresistor and the permanent magnet modifying the magnetic field coupled with the sensible area of the magnetoresistor. In conclusion the force applied to the structure produces a resistance variation on the sensor output.

Three magnetoresistive force sensors are placed in the polyethylene insert as shown in Fig. 1. Their placement have been chosen on the particular geometric shape of the human knee implant; two of them are close to the two condyles that represents the contact areas, through which the forces are transmitted and a third has been placed in the central part equidistant to the two condyles.

In Fig. 2 a block diagram of the autonomous sensor and the readout unit is shown. The autonomous sensor has three magnetoresistors R_left, R_central, R_right (R_L, R_C, R_R), a low-power microcontroller and a transponder. The low-power microcontroller chosen is the Freescale 9S08QB8, that includes a 12-bit ADC (Analog to Digital Converter), and a 128 kB flash memory. The transponder (U3280M) is produced by Atmel and its working frequency is 125 kHz. It consists of a rectifier stage for the antenna, a power manager, a damping modulator and a field-gap detection stage for RF communication.

The readout unit consists of a transceiver (U2270B) produced by Atmel. This component drives the coil antenna and demodulates the digital signal. The transceiver is connected to a microcontroller (Freescale 9S08AW60). The readout unit is supplied by an external power.

An electromagnetic field is generated by the readout unit and received by the autonomous sensor. The field is modulated by the both units to communicate each with the other. The energy of the same electromagnetic field is used by the autonomous sensor as a power source. The advantage of transmitting an electromagnetic field at such comparatively low frequency is the possibility to transfer more effectively data and energy through the human body.

3. Description of the measurement method

The force applied to the implant generates a deformation measured by the three magnetoresistor sensors previously described. The deformation–resistance curve of a magnetoresistor has been studied and evaluated experimentally by using an experimental apparatus to control the distance between the magnet and the magnetoresistor and contemporary measuring the resistance and magnetic field on the sensor. Measurements were obtained at about 25 °C. A micrometric screw moves the magnet with respect to the magnetoresistor, and the relative distance was measured by a laser displacement sensor (optoNCDT 2200, ILD 2200-2, Micro-Epsilon Corporation) which has a measuring range of 2 mm, a resolution of 0.0015% F.S.O. and a linearity of 1 µm. The resistance values were measured by a multimeter (Fluke 8840A); the magnetic field is measured by a commercial linear Hall Effect sensor (MLX90251) with accuracy better than 1%. A mechanical structure, consisting of a micrometer screw that moves an L-bracket made by plastic material, was used. The magnet and the material with high permeability were fixed to the bracket and the magnetoresistor was positioned below. By varying the micrometric screw, the distance from the magnet and the magnetoresistor was changed and measured with the optical sensor. Afterwards, the Hall Effect sensor was positioned and field measurements were performed. Fig. 3 shows the resistance (a – blue circles) and the magnetic field as a function of the distance between the magnet and the magnetoresistor (b – green squares). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

Interpolating the experimental data of Fig. 3 (a – blue circles), expression (1) can be obtained,

$$D = 7.868 \times 10^{-6} R^2 - 3.107 \times 10^{-1} R + 3082 \quad (1)$$

where the distance (D) is measured in micrometers and the resistance (R) in ohms.

The magnetoresistor mounted on the prosthesis, when no force is applied, has a value of approximately 12.5 kΩ (in the following referred as R_o) corresponding of about 420 µm of distance from

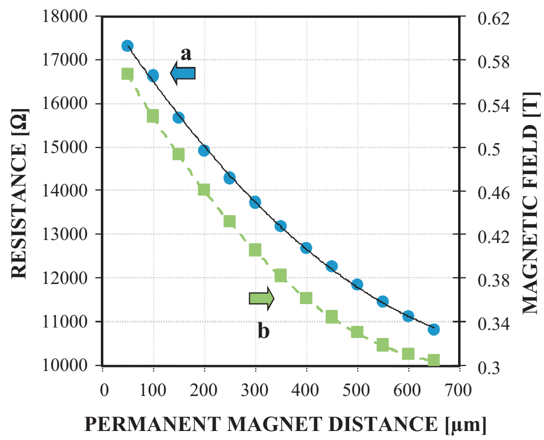

Fig. 3. Experimental values of the resistance of the magnetoresistor (a) and experimental values of the magnetic field (b) for different distances between magnet and magnetoresistor.

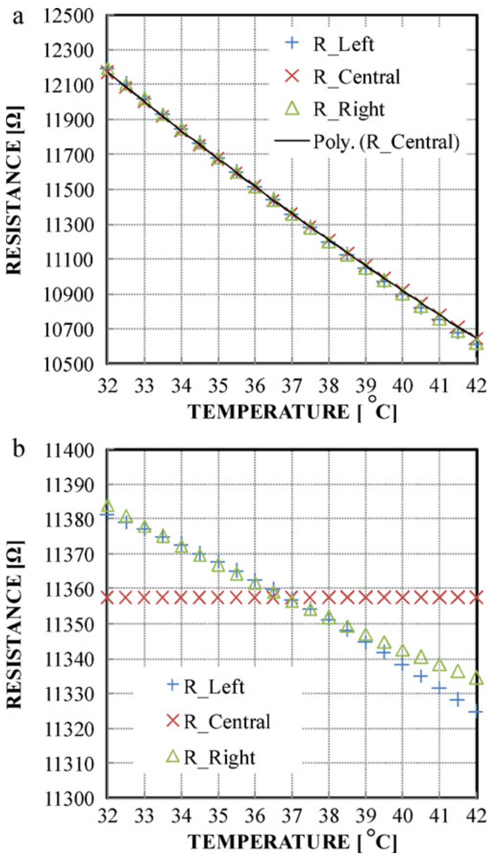

Fig. 4. Experimental results of resistance variation as a function of temperature. (Data not compensated (a) and after mathematical compensation (b).) Please note that the scale of (b) is enlarged.

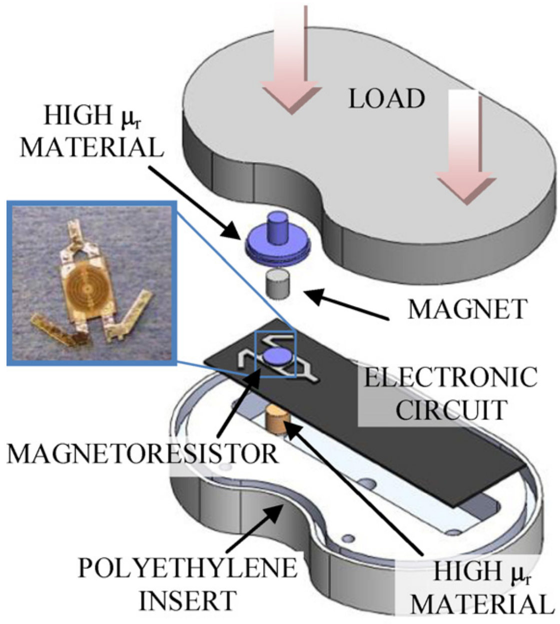

Fig. 5. Basic structure of the device for the characterization of the magnetoresistive sensors.

the magnet. When a load of 3 kN is applied to the condyle area of the prosthesis, the distance is reduced to about 200 μm. If the distance variation around the initial value of 420 μm is considered, it is possible to obtain a relationship between the distance variation and the resistance variation $\Delta R = R - R_0$,

$$\Delta D = D - 420 = -0.11\Delta R + 7.8 \times 10^{-6}\Delta R^2 \qquad (2)$$

The magnetoresistor output depends on temperature. Since inside the human body the temperature increases of about 3 °C after, for example, 45 min of normal walking [11], a slight variation of temperature can be expected. Experimental tests were done in order to analyze the temperature drift and to compensate the possible variation of the sensor resistance. The values have been obtained by using a controlled temperature chamber (UC 150/70–Perani). The resistances of the three magnetoresistors and the resistance of a reference temperature sensor (Pt1000) were measured by four multimeters (Agilent 34401A) connected by GPIB cables and operated by software. The chamber temperature has been set between 15 °C and 50 °C for 2 h, mainly focusing the attention close to 37 °C. Fig. 4 (a) shows the resistance of each magnetoresistor as a function of temperature in the interval from 32 °C to 42 °C. As can be expected, the data show that the three magnetoresistors have the same temperature dependence. Eq. (3) describes the resistance temperature drift of R_central (interpolated curve in Fig. 4(a)) due to a temperature variation ($\Delta T = T - T_0$) where T_0 is referred to 37 °C,

$$\Delta R_{\text{thermal}} = 1.868 \times \Delta T^2 - 152.4 \times \Delta T \qquad (3)$$

The resistance drift is equal to about 150 Ω each centigrade. Since the experimental results show a strong dependence of resistance on temperature, in order to have accurate measurement values Eq. (3) can be used to compensate the thermal drift.

Fig. 4 (b) reports the data of Fig. 4 (a) as results of the compensation. In the final implementation, the temperature is measured by a temperature sensor integrated in the autonomous sensor. During the measurement activity, the microcontroller measures the three resistances, the temperature and eventually compensates the resistance data.

The relationship between force applied to the insert and deformation of the structure measured by the magnetoresistors has been experimentally evaluated. For this purpose, in Fig. 5 a basic structure for the measurement of the magnetoresistive sensor outputs when different forces are applied to the structure is shown. It has been made by UHMWPE and has the same geometry of the real insert. A specific machine (Instron 8501) was used for load application; the control is obtained using LabVIEW and a specific hardware (Instron 8800). Through a mechanical structure built ad hoc, the forces are applied to the femoral component placed on the polyethylene insert (Fig. 1). The force control and the measurement of the distance variation are made by a load cell and an LVDT integrated and controlled by the Instron. During the tests with the Instron, the resistance values of three magnetoresistors were measured with three multimeters connected via GPIB.

In Figs. 6 and 7 the experimental results are shown. Two different situations have been replicated: the first [19] considers the loading on the implant due to an heavy physical activity such as jumping, for example and this case occurs not frequently; the second keeps in consideration a normal walking that is a common and frequently case. In the first case it is assumed that the applied forces can be changed in the range 0–3000 N. The data are reported in Fig. 6 and as it can be seen the system shows a hysteretic loop due to the geometry and physical characteristics of the polyethylene insert. The second case has been arranged applying force that consists of a static component of 800 N plus a sinusoidal component of amplitude 200 N. Fig. 7 shows the corresponding data. The experimental setup used to obtain the data of Fig. 7 (a) is the same used for the results shown in Fig. 6, initially the magnetoresistors were mounted within the prosthesis and with no external forces applied, then a static component of 800 N plus a sinusoidal component of amplitude 200 N were applied. As shown in Fig. 7 (b), the central magnetoresistor is less dependent on the forces

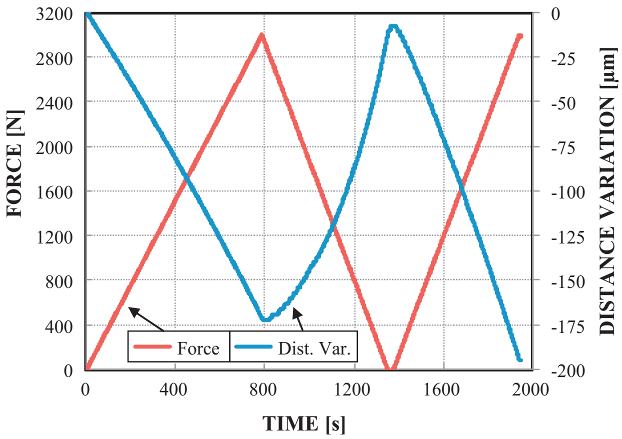

Fig. 6. Experimental results of the forces applied to the insert and distance variation of the femoral component.

applied as expected, because the central part of the insert is not in direct contact with the femoral component (Fig. 1). From the force data reported in Fig. 7 (a) and the resistance data R_right of Fig. 7 (b), a relationship between force variation, considering that when no force is applied the resistance is R_0, and resistance variation $\Delta R = R - R_0$ can be obtained,

$$F = -0.00035 \times (\Delta R)^2 + 2.15 \times (\Delta R) \quad (4)$$

The units of the force are in Newtons and the resistance in ohms.

Considering the previous investigations, in the autonomous sensor a simple procedure was implemented for force measurement. The three resistances are measured by the magnetoresistors, each value may be temperature compensated using expression (3), and subsequently the force values are given by Eq. (4).

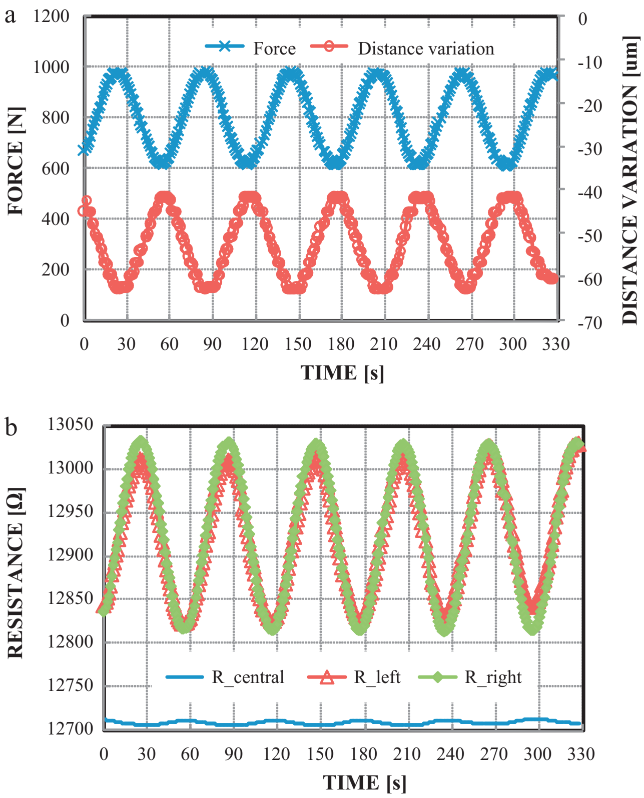

Fig. 7. Dynamic tests (a) force variation and (b) resistance variation.

4. Description of the electronics

Resistive sensors are often connected in a Wheatstone bridge to increase sensitivity and compensate the drift due to temperature such as [21]. In order to reduce the volume to host the system inside the prosthesis, a simpler configuration, using only one magnetoresistor and one resistor has been implemented as shown in Fig. 8. In this case, the resistance measurement uses a ratiometric technique, compensating the V_{ref} changes while the temperature drift is compensated by software through a direct temperature measurement and using Eq. (3). As reported in Fig. 8, three magnetoresistors have been placed on the autonomous sensor layout, one central (R_C) and the other two laterally (R_L and R_R). For each magnetoresistor, the resistance values are obtained measuring the voltages of the voltage divider. As example, the resistance value R_R is obtained measuring the voltage V_R and then, applying the following expression.

$$R_R = R \times \frac{V_{ref}}{V_R} - R \quad (5)$$

The resistance R has a fixed value of 15 kΩ, V_{ref} is 2 V. Resistor R is a 1% SMD resistor with a temperature coefficient of about 100 ppm/°C, and it is neglectable, since it is two orders of magnitude less than the same coefficient of the magnetoresistor. The same equation can also be written for the other magnetoresistors.

The autonomous sensor measures three resistances and then provides the magnitude of the tibiofemoral compressive force.

To transmit data, the transponder (U3280M – 125 kHz) modulates the magnetic field using a damping stage; in particular the OOK (On–Off Keying) modulation and the Manchester code are chosen. One device pin (clock extractor) is used to provide a clock signal for the synchronization of data transfer. The transponder interface can also receive data; the readout unit modulates the data with short gaps in the field and a gap-detection circuit reveals these gaps and decodes the signal. Furthermore, the device is able to generate a power supply, handled via electromagnetic field and the coil antenna of the transponder interface. In the autonomous sensor implementation, the transponder (U3280M) is not supplied by batteries; no battery is used inside the polyethylene insert. The electromagnetic field generated by the readout unit is used both as a means for transmitting signals and as a power source. The autonomous sensor antenna has an inductance of about 640 µH, and the readout antenna has a diameter of about 120 mm and an inductance of about 3.3 mH; both are built by wrapped wire. The low-power microcontroller (9S08QB8) has a timer unit making it possible to synchronize the data transmission. The microcontroller has a low-power configuration; all the unused peripherals are switched off. To maintain the power consumption low, the clock of the microcontroller is 500 kHz during the measurement and transmission, whereas the clock is 16.4 kHz during stop mode. The typical activities of the autonomous sensor are defined as stop, measure, transmission (Fig. 9). The stop mode has a duration of 6 s; the measure conversion and the transmit mode is about 6 ms and 7 ms, respectively. The digital data of the resistance are transmitted using 16 bits; each resistance is obtained mathematically using Eq. (5), and the temperature is transmitted with 16 bits. The external readout unit consists of a read/write base station (U2270B), able to supply power to the transponder by generating a magnetic field through its antenna. A signal generator produces a sine wave voltage of up to 80 Vpp at a frequency range of 125 kHz. Furthermore, the base station demodulates the signal from the transponder and converts it into a digital signal. Supply voltage is 12 V, as indicated in Application 2 of the datasheet. The operating voltage of the microcontroller (9S08AW60) is 5 V and the bus frequency is 7.38 MHz. A timer unit is used to decode the demodulated signal and the data collected are transferred to a personal computer (PC) using a serial communication interface (SCI).

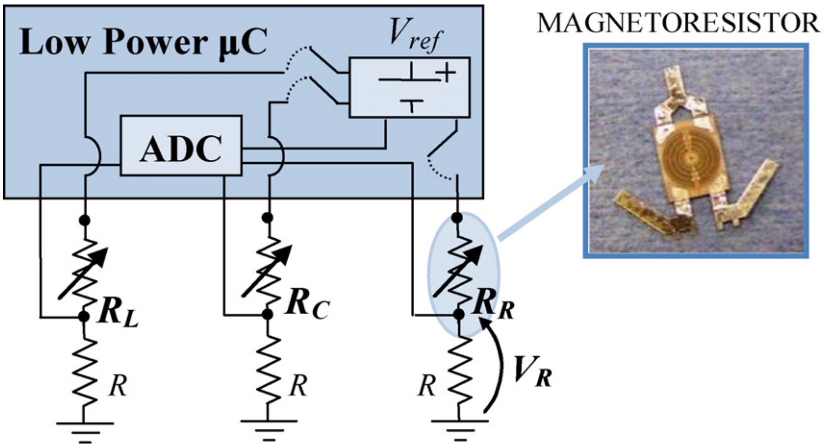

Fig. 8. Block diagram of autonomous sensor system and readout unit.

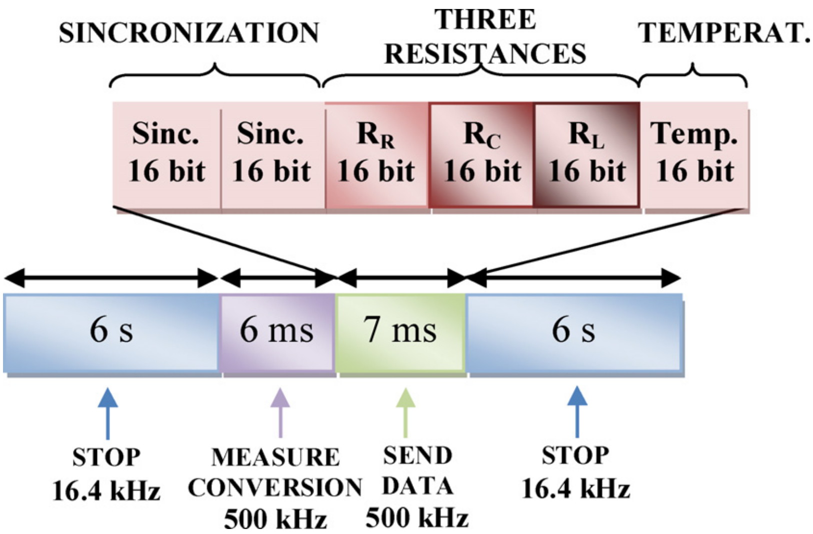

Fig. 9. Typical autonomous sensor activities.

5. Experimental results

In this paragraph, experimental results of a preliminary evaluation of the autonomous sensor system are reported. An experimental setup, shown in Fig. 10, consists of: an Instron 8501 machine, a Lecroy LT374M oscilloscope, a Fluke 88740A multimeter and a PC. The Instron 8501 machine is used to generate a controlled force applied orthogonally on the femoral component. The multimeter monitors the powering levels of the internal circuit and the oscilloscope monitors the transmission signals. The readout unit is connected to an external inductor and positioned as reported in Fig. 10.

For a future phase of in vivo measurements, the coil can be slipped over the patient's leg and fixed with a belt and a receiving circuit can demodulate the signals for computation and storage. The data can be monitored in real time using the PC.

Using the experimental setup, the system was tested applying orthogonally different forces, in a range up to 3 kN. In Fig. 11, the forces generated by the Instron and those measured by the autonomous sensor are reported for a wide range 0–3 kN. Only the data measured by the magnetoresistor R_R are reported, for which the characterization was made. The measured data have variability in measurements; possible variability hypotheses are under investigation including the nonlinear behavior of the material and hysteresis effects, and refining the temperature compensation. The wireless transmission characterization is achieved by monitoring data and the levels of voltage through the multimeter and the oscilloscope. The force characterization is obtained using the PC with LabVIEW software. During the wireless transmission characterization no force is applied to the prosthesis. The data collected by the readout unit are transferred to a PC that control the process by a dedicated software developed with LabVIEW. Power consumption measurements are reported in Table 1 during the different activities (measurement, transmission and stop mode), when the autonomous sensor is powered continuously by the external readout unit. In the performed tests, the autonomous sensor, powered by the readout unit, can send the measurement data to the readout unit every 6 s. In this situation, the microcontroller and the transponder require a power supply of about 1.7 mW, with a current consumption of about 0.85 mA and a voltage level of about 2 V. In Fig. 12, the wireless transmission signals are monitored during

Table 1
Power consumption measurements.

Activity	Voltage [V]	Current [µA]
Readout unit – transceiver communication	12	19,300
Autonomous sensor – measurement and transmission	2	850
Autonomous sensor – stop mode	2	160

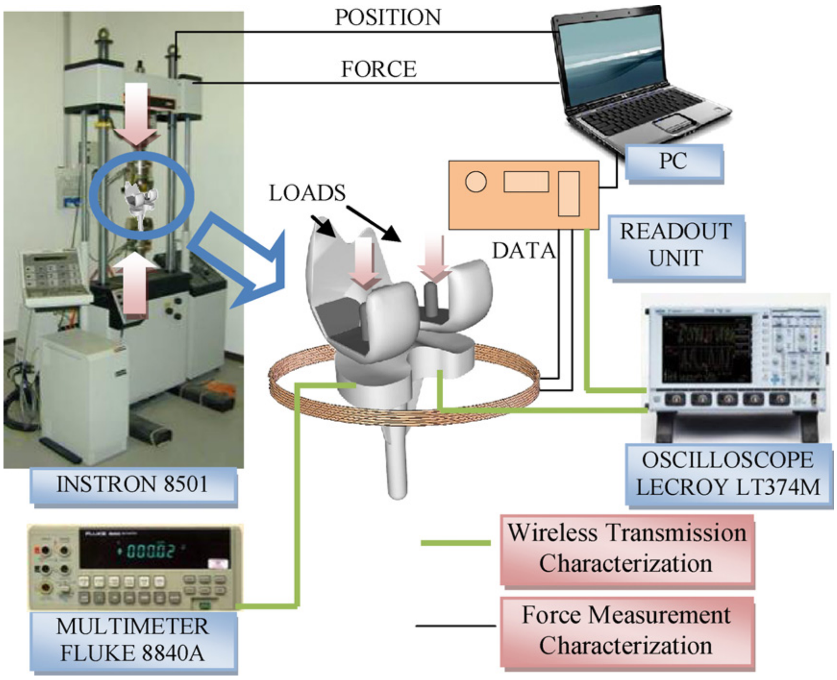

Fig. 10. Block diagram of the experimental setup for the characterization.

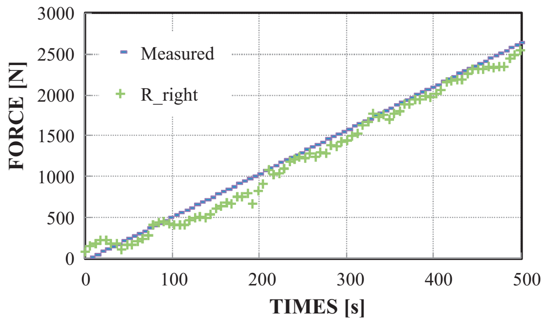

Fig. 11. Force values calculated by the autonomous sensor and compared with the forces measured by the Instron.

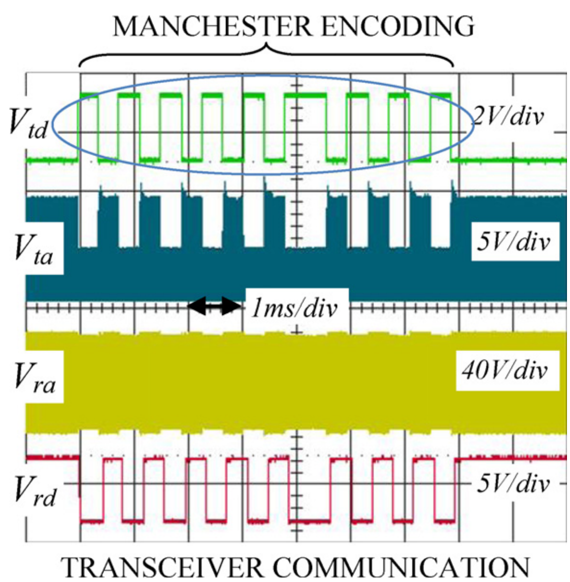

Fig. 12. Wireless transmission signals of the converted data and typical autonomous sensor activities.

communication and stop mode. In Fig. 12, the signals are reported when the RF field supplies the sensor. The signals are the differential voltage of the reader antenna (V_{ra}), the transponder antenna voltage (V_{ta}), the transmitted data (V_{td}), and the received data (V_{rd}).

6. Conclusions

In this article, the autonomous sensor proposed for force measurements in human knee implants was presented. The experimental results showed that the sensor represents a promising new system for medical implants in vivo force monitoring. Some authors have suggested that contact areas and pressures within TKA prosthesis (Total Knee Arthoplastic) can be predictors of wear and failure of the tibial inserts made by ultra-high molecular weight polyethylene (UHMWPE). Since the proposed device permits the in vivo measurements, it is possible to have information on the mechanical insert behavior. The autonomous sensor could lead to an improvement regarding the knee implant function and the treatment of patients with total knee implants. Furthermore, the hysteresis phenomenon that has been analyzed in this manuscript could in part explain the variability of the results. However, this variability can still achieve a good accuracy in the force measurement. In a possible future development it is expected to adopt fabrication techniques and design strategies that can reduce or completely mitigate the hysteresis phenomenon.

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