

Measurement of Stress Levels in Knee Implants Using Wireless Sensor Technology

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ABSTRACT: This paper explains the development of a prototype to measure the stress levels in knee implants using various sensors. Different sensors are used to monitor the force which is applied on the implant, to track the flexibility, direction and temperature. The sensing elements which are hermetically sealed using laser welding techniques are used to detect the overload in the implant. The sensors are designed in order to monitor these values up to a certain limit and if these values exceed, then buzzer will turn ON and a SMS with GPS location and exact readings will be sent to the patient as a warning sign as well as to the Physician in charge. The Buzzer is used to give alert to the patient, when the sensor value crosses the limit. The message is to alert the patient to avoid overload of the implant beyond certain limit. The LCD is enabled by the PIC controller and displays the values of the sensors which are mounted or welded on the polyethylene implantation

KEYWORDS: arthroplasty, sensors, stress, flex, PIC controller, GPS

I. INTRODUCTION

Knee replacement, also known as Total Knee Arthroplasty(TKA), is a surgical procedure to replace the weightbearing surfaces of the knee joint to relieve pain and disability. Total knee replacement has proven to be extremely successful and beneficial and a significant contribution to modern surgery. It is most commonly performed for osteoarthritis. The surgery is a complex procedure that requires extensive pre-operative planning, specialized implants and tools, prolonged operating times and mastery of difficult surgical techniques. It usually takes longer to perform than the original knee replacement. It is composed of the following stages:

- **Pre-surgery:** Preparation includes X-rays, laboratory tests, knee aspiration and in some cases additional assessments, such as bone scans, CT scans or magnetic resonance imaging (MRI).
- **Surgery:** The implant is removed and bone grafts may be used to fill larger areas of bone loss. In some cases, metal wedges, wires or screws may be used to strengthen the bone. Finally, specialized revision knee implants are inserted.
- **Post-operative care:** This is very similar to the care of the original knee replacement. It includes a combination of physical therapy, blood management and pain medication. A brace or splint may be used to protect the joint after the surgery.

While most knee replacements will function well for years, patients should be aware of the signs of failure, including increased pain or decreased function that may require a corrective procedure known as revision total knee replacement, if necessary. A failed knee implant is usually caused by wear and tear with subsequent loosening of the implant. Other causes are infection, instability, fracture, or stiffness. The most common symptoms of a failed knee implant are pain, instability, swelling and stiffness across the entire knee (generalized) or in a small section (localized). Although knee

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replacements normally perform well for at least 15-20 years in more than 95 percent of patients, there are five primary reasons why a knee implant fails:

- **Wear and loosening:** Friction caused by joint surfaces rubbing against each other wears away the surface of the implant causing bone loss and loosening of the implants.
- **Infection:** Large metal and plastic implants can serve as a surface onto which bacteria can latch.
- **Fracture:** Fractures around the knee implant that disrupt its stability may require revision surgery.
- **Instability:** A sensation of the knee "giving away" may mean that the soft-tissue surrounding the knee is too weak to support standing and walking. Improperly placed implants may also cause instability.
- **Stiffness:** Loss of range of motion which causes pain and a functional deficit.

Extensive research is being carried out on how to improve the survival rates and prolong the lifespan of the implant. In addition, early detection of high wear rates allows for anticipatory treatment, which could eventually prevent premature implant failure. The most probable cause of premature implant failure is aseptic loosening, which is a severe physiological response to foreign debris in the joint. This debris is generated from abrasive wear in the ultra-high molecular weight polyethylene (UHMWPE) of the tibial insert, due to malpositioning of the articular surfaces and the high forces acting in the joint. Therefore, effective monitoring of the active stresses within the UHMWPE insert can provide a clearer perception of knee biomechanics, and provide real-time observation on the condition of the knee implant. Many attempts have been made at designing implantable monitoring systems. In this paper, sensors to monitor the parameter levels along with warning system have been proposed.

II. ANALYSIS OF THE CAUSES OF FAILURE OF ARTHROPLASTY

Previous studies of failure mechanisms leading to revision total knee replacement (TKR) determined that many failed early, with a disproportionate amount accounted for by infection and implant-associated factors including wear, loosening and instability. Since then, efforts have been made to improve implant performance and instruct surgeons in best practice. Aseptic loosening was the predominant mechanism of failure (31.2%), followed by instability (18.7%), infection (16.2%), polyethylene wear (10.0%), arthrofibrosis (6.9%) and malalignment (6.6%). The mean time to failure was 5.9 years (ten days to 31 years), 35.3% of all revisions occurred at less than two years, and 60.2% in the first five years. With improvements in implant and polyethylene manufacture, polyethylene wear is no longer a leading cause of failure. Early mechanisms of failure are primarily technical errors. Loosening is one of the most common complications resulting from a faulty device. This occurs when components of an implant begin to separate from the bone. Soft tissue instead of bone can grow in between the components and the bones, creating instability and pain in the joint. Loosening is natural over time, but it usually does not occur for several years. In poorly designed devices, it can occur in a year or less. Some manufacturers have blamed the device failure on the surgeons despite the fact that some of their models show higher than normal revision surgery rates regardless of the surgeon who implanted them.

Symptoms of Failure Pain

When prosthetic components begin to fail, issues such as fracture of the plastic spacer located between the metallic thigh bone and shin bone implants can occur from abnormal wear patterns or improper surgical techniques. Plastic fracture fragments can dislodge and become stuck between these surfaces, causing pain and mobility problems. Pain can begin as a mild soreness, or it can be severe if the fracture of the plastic occurs suddenly.

Swelling

Swelling occurs as a result of inflammation of the lining of the knee, which in turn stimulates production of fluid. This is the body's response to irritation, causing swelling in your knee. This irritation is frequently caused by the presence of microscopic pieces of plastic in the knee fluid, as well as the instability caused by loosening of the joint.

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Instability

Instability in the knee often feels like the knee wants to give out with standing or walking. This is frequently caused by excessive wear of the plastic spacer, causing it to be thinner than it was at the time of surgery. Ligaments become loosened, making your knee joint less stable.

Warmth

In addition to the swelling that can occur, another symptom of a failing prosthesis can include noticeable warmth of the joint. Replaced knees can exhibit warmth in the joint for months after surgery, but this effect steadily decreases over time. The warmth associated with prosthetic failure can often be significant and associated with a level of redness of the skin caused by inflammation

III.LITERATURE ON IMPLANTABLE SYSTEMS FOR MONITORING BIO MEDICAL IMPLANTS

Valuable efforts have been made to design implantable systems for monitoring biomedical implants, either using strain gauges, fiber Bragg gratings or Tekscan sensing systems (Taylor et al. 1998; Kirking et al. 2006; Heinlein et al. 2007; Mohanty et al. 2007). Though the systems have their specific advantages many require alterations of the current prosthesis designs or can only be used during surgery not being suitable for implantation. To overcome this limitations sensors can be fabricated using biocompatible materials, such as polyimide, and embedded into the polyethylene insert without introducing design changes (Crescini et al. 2009,2011). Polymer-based microelectromechanical systems (MEMS) are increasingly being used in biomedical applications (Grayson et al. 2004) and, recently, micro-machined polyimide sensors have been used as sensing elements in a broad range of biomedical applications, e.g. deep brain recording and stimulation (Mercanzini et al. 2008) and contact lens pressure sensors for glaucoma (Leopardi et al. 2009).

IV.MEASUREMENT OF STRESS LEVELS IN KNEE IMPLANTS USING WIRELESS SENSOR TECHNOLOGY

Wireless sensor technology is useful for long term detection of physical quantities within the human body as a part of treatment assessment, disease diagnosis, or detection of biomedical implant failures. Physical parameters such as pressure, stress, strain and fluid flow within the human body are critical indicators for detection of many diseases. Today, many physical parameters in the human body are measured indirectly via *ex vivo* methods such as sphygmomanometers and ultrasound techniques. Although simple and noninvasive, the use of *ex vivo* techniques to predict *in vivo* mechanical mechanisms often fails to deliver reliable and localized analytical results. A technique to obtain accurate results is to insert the sensor into the human body via catheter and to perform *in vivo* measurements. The major limitation of using the catheter-based measurement technique is that it often requires the patient to be sedated, which may not reflect the actual conditions during the patient's daily activities. This may result in poor prognostic and diagnostic outcomes. An alternative technique to perform *in vivo* measurements without disrupting the patient's normal activities is the use of implantable biosensors. The sensor is first implanted at the site of interest, with data collected and remotely transmitted to an external recorder in real time. Upon completion of the measurement, which can be as short as a few hours or as long as a few years, the sensor is then removed. The advantages of implantable biosensors are that they can directly track the parameters of interest at the local sites without interrupting the patient's normal activities. The use of implantable biosensors may also reduce the chance of developing infections since there is no need for wires perturbing from inside the body for data collection. Although their popularity has increased, implantable biosensors are relatively new technologies and are mostly used for orthopedic applications with stress/strain monitoring.

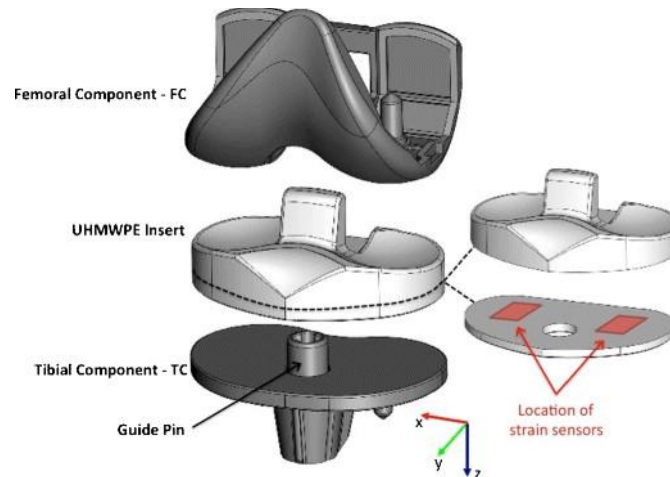


Figure 1 Knee Implant Model

V.COMPONENTS

Temperature Sensor

When walking long distances, the knee prosthesis heat up due to friction. The influence of articulating materials and lubricating properties of synovia on the final temperatures, as well as any potential biological consequences, are unknown. Measurement of the implant temperatures will caution the patients of poor lubricating properties which may be at risk for thermally induced bone necrosis and subsequent implant failure. The implant temperature is measured with an accuracy of 0.1°C in a range between 20°C and 58°C.

Force Sensor

One of the most affected components of the artificial knee implant is the ultra-high-molecular-weight polyethylene (UHMWPE) insert, due to its geometry and the high forces acting upon it. Therefore, monitoring the strain, associated to knee imbalance and forces acting upon the prosthesis, can give continuous feedback on the status of the artificial knee implant. MEMS strain-sensing device is used for the monitoring of loads acting upon an artificial knee implants, at the level of the UHMWPE insert. The sensors are based on polyimide-metal-polyimide sandwich structures that are embedded into the UHMWPE part.

Flex sensor

The flex sensor is a thin strip, around 4.5 inches in length that issued to monitor the user's knee joint angle. When the device is attached on the knee and bent, the flex sensor circuitry will output unique output voltage which will describe the user's range of motion. Evaluation of the flex sensor data can help confirm that the patient is exceeding limits in knee extension and knee flexion.

Integration of sensor readings

Control Unit

The control unit is responsible for controlling all of the sensors, feedback devices, and power source. It is also responsible for logging data from the sensors for post-processing and analysis.

Microcontroller

The microcontroller is responsible for controlling all the feedback devices in the system as well as collecting and interpreting data from the sensors. It will also control components of the power supply to manage the power

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consumption of the device. It consists of the software that is capable of choosing modes of the device from everyday mode, exercise mode or inactivity mode.

Transformer

As the major electronic device run in the DC, the construction of a power supply is necessary. The uses step-down transformer for stepping down the 220V AC to 12V AC. A bridge rectifier is used to rectify the 12V AC into 12V DC. The IC regulator is used to convert 12V DC to 5V DC. The power supply is getting constant 5V DC as output. The sensors are optimized for small quantity measurements, and has a high sensitivity in a wide measuring range.

Power supply

The power supply and sensors are connected to PIC controller. The 5V DC is given input to PIC microcontroller. It has 40pin IC. The only 35 single-word instructions to learn. The Operating speed is DC – 20 MHz clock input and DC – 200 ns instruction cycle. Up to 8K x 14 words of Flash Program. Memory, Up to 368 x 8 bytes of Data Memory (RAM), Up to 256 x 8 bytes of EEPROM Data Memory. Pinout compatible to other 28-pin or 40/44-pin PIC16F877A microcontrollers. The LCD and GSM is connected to PIC microcontroller.

GSM Module

PIC drives LED, measures a signal from NPN transistor by using 10 bit A/D converter, and communicates with a Mobile Station via GSM module. Power supply for whole device is stabilized to 3.3 V with step-down voltage stabilizer. Wireless communication electronics based on GSM standard, by which the sensing part of the system communicates with a Mobile Station, is developed for the sensors. Here using 16x2 LCD display for displaying output. As a light source and detector, LED and transistor are used. High power LED, BC 547 with the peak wavelength of 660 nm, and NPN transistor produced by Industrial Fiber Optic, Inc are used. The transistor provides a very high optical gain, eliminating the need for the post amplification.

How the System works

The idea is to integrate force and temperature sensors and accelerometers inside the prostheses. These sensors can then be used for the in-vivo detection of imbalances, kinematics and implant micro-motions, joint orientation and bone-implant friction. With this electronic prosthesis, all you have to do is get the patient to walk around for a short while and analyze the data collected. You can then adjust the physiotherapy and rehabilitation program accordingly, focusing on the part of the body that requires treatment. Thus, we will have the explanation for certain phenomena that occur in the prosthetic joint in real time. Eventually, this information could even help us to create prostheses that can be customized according to the patient's age. We have to package, compile and miniaturize sensors so that they can be inserted into existing prosthesis models. An analog front-end circuit also has to be integrated, as does a microprocessor and a wireless RFID system. This micro engineering must enable the device to transmit data while consuming just a few microwatts of energy.

The sensors are designed in order to monitor the customized values and if these values exceed, then buzzer will turn ON and a SMS with GPS location and exact readings will be sent to the patient as a warning sign as well as to the Physician in charge. The Buzzer is used to give alert to the patient, when the sensor value crosses the limit. The message is to alert the patient to avoid overload of the implant beyond certain limit. The LCD is enabled by the PIC controller and displays the values of the sensors which are mounted or welded on the polyethylene implant.

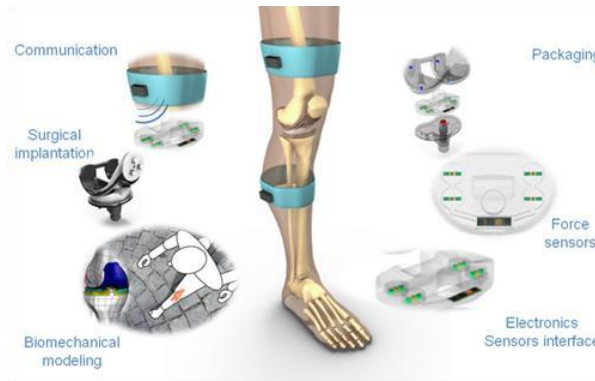


Fig.2 The System

VI.CONCLUSION

The most probable cause of premature implant failure is aseptic loosening, which is a severe physiological response to foreign debris in the joint. This debris is generated from abrasive wear in the ultra-high molecular weight polyethylene (UHMWPE) of the tibial insert, due to malpositioning of the articular surfaces and the high forces acting in the joint. Therefore, effective monitoring of the temperature, force and flex within the UHMWPE insert can provide real-time caution on the condition of the knee implant to the patient.

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