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***In-Vivo* Polyethylene Wear and Knee Prosthesis Longevity Estimation**

Deepak Gupta, Shaban Almouahed, Cyril Lahuec, Matthieu Arzel, Michel Jezequel and Chafiaa Hamitouche

Abstract— This paper describes an *in-vivo* polyethylene wear and knee prosthesis longevity estimation approach using an implantable ligament imbalance metric system. Four piezoelectric elements are used to measure the axial force components, on the tibial tray surface and their center of pressure is calculated. This can be used, along with a knee simulator, to estimate polyethylene wear, and the state of the implanted knee prosthesis. Surgeons can exploit this to improve the post operative rehabilitation measures, whereas prosthesis manufacturers can use it to improve prosthesis's strength, geometry and life. The proposed self-powered measurement and telemetry system does not require any external power.

I. INTRODUCTION

One of the most common problem with the knee joint is the deterioration of cartilage (meniscus) between femoral and tibial bones. These tissues have limited capacity of self-restoration and their wear and tear is one of the principal reason of osteoarthritis. The severe cases are usually treated through a Total Knee Arthroplasty (TKA) during which an artificial knee prosthesis made up of a femoral component, a polyethylene (PE) insert emulating the meniscus and a lower tibial tray is fitted. However, among the millions of TKA conducted worldwide, over a period of time the PE component starts wearing due to various reasons such as malalignment, erosion etc. This results in an asymmetrical PE surface which ultimately induces the collateral ligament laxity. As a consequence, the point on the tibial tray where the net axial force is exerted, offsets further. This may result in change of contact area between the condyle contact point and the tibial plateau surface. This has an impact on the contact stress and consequently the polyethylene wear rate [1] - [3]. Hitherto, most of the methods used, to estimate the PE wear rate and *status quo* of the already implanted prosthesis, are indirect and approximative.

In this work, we propose an approach to estimate and predict the PE wear and the longevity of the already implanted knee prosthesis. For this, an implantable ligament imbalance measurement system can be used along with a knee simulator. The results will help prosthesis manufacturer to improve overall prosthesis design and the surgeons to identify a potential prosthesis failure and take corrective or precautionary measures. In section II the existing measurement techniques are briefly described. Section III explains the ligament imbalance measurement system and its usage

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to determine the PE wear. Section IV throws some light on the possibilities and perspectives in the long term. Section V concludes the paper.

II. EXISTING TECHNIQUES TO MEASURE THE PE WEAR AND KNEE FORCES

In order to measure PE wear rate and to estimate life of a knee prosthesis, multiple techniques exists and could be *in-vivo* or *in-vitro* or even a combination of both. The existing techniques can be broadly categorized into the following.

A. Retrieval Analysis

Retrieval analysis is a straightforward technique in which a used or failed prosthesis is evaluated to measure the polyethylene wear using statistical methods. Since this technique analyzes already "failed" specimens, are of little use for an early assessment of a newly implanted prosthesis. Furthermore, it is generally accepted these analyses results are only approximative and may overestimate wear [4].

B. Radiography

In this, relatively simple method, plain X-rays of the implanted prosthesis are taken for different angles and positions. These are then studied for any aberration from the normal silhouette of the implanted prosthesis. However, the accuracy is limited due to parallax error [5]. Improved X-ray techniques extracts three-dimensional (3-D) images of an implant from a single perspective and are then matched against highly accurate geometrical model of the implant, which is known, *a priori*. However, the disadvantage is inaccuracy and the subject has to be X-rayed many times which could be hazardous. Another *in-vivo* measurement techniques for PE wear, based on 3-D image and Roentgen Stereophotogrammetric Analysis (RSA) is reported in [6].

C. Knee motion analysis

Knee motion analysis techniques are used to measure the bone, cartilage positions and their relative motions. The results are matched against their pre-defined mathematical models. These techniques include the electrical linkage method in which one or more potentiometers are used to measure voltage changes caused due to rotation or linear translation and thus predicting the bone movements. For this, both *in-vivo* and *in-vitro* methods have been developed using implanted markers or anatomical landmarks. Video techniques are also used to measure joint motion, in which markers are attached to the limb segments and their relative motion is captured with different cameras. In fluoroscopy, images are matched against a pre-registered library of three-dimensional images of the tibial and femoral components of

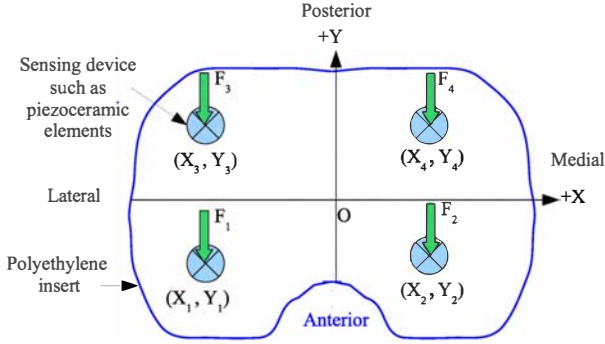


Fig. 1. Tibial tray with X and Y axes taking the center of the stem as origin. Sensing devices are located to obtain the axial force distribution in the medio-lateral (M-L) and the anterior-posterior (A-P) directions.

the prosthesis. These techniques largely rely on the accuracy of biomechanical analysis and a rough estimation of PE wear is achievable, though it is difficult to recover the volumetric losses.

D. Biomechanical Measurement

Other set of techniques include, methods focusing on biomechanical parameters such as axial force, ligament laxity measurement and then infer their impact on PE wear. An *in-vivo* system for distribution of axial force measurement was developed by Kaufman *et al* [7]. Another technique for the *in-vivo* knee load measurement with telemetry were proposed in [8] [9]. In this the stem of the artificial prosthesis was instrumented with strain gauges to measure the axial forces and moments. A micro-transmitter was also housed in it, which processes the sensed data and transmit it to an external receiver. Though interesting, the biggest inconvenience of this method is an external induction coil wrapped around the knee to power the implanted electronic system. Hence, making it usable only under strict supervision. In addition, knee simulators are used to emulate the knee motion and observe their impact on the artificial prosthesis longevity by measuring the wear and tear rate of PE. A recent *in-situ* study by Kretzer *et al* [3] attempted to quantify the effect of joint laxity on polyethylene wear.

In order to facilitate an early assessment of a newly implanted prosthesis, estimate and predict the PE wear and the longevity of the implanted prosthesis, the *in-vivo* autonomous ligament imbalance measurement system in combination with *in-situ* experiments is envisaged.

III. AUTONOMOUS LIGAMENT IMBALANCE MEASUREMENT SYSTEM

A. Metrics

In [10], the authors have calculated the center of pressure (COP), as the barycenter of the axial force applied at the tibial tray, using force sensing elements (Fig. 1). COP_X and COP_Y are calculated in the medio-lateral (ML) and in anterior-posterior(AP) directions respectively. Generic ex-

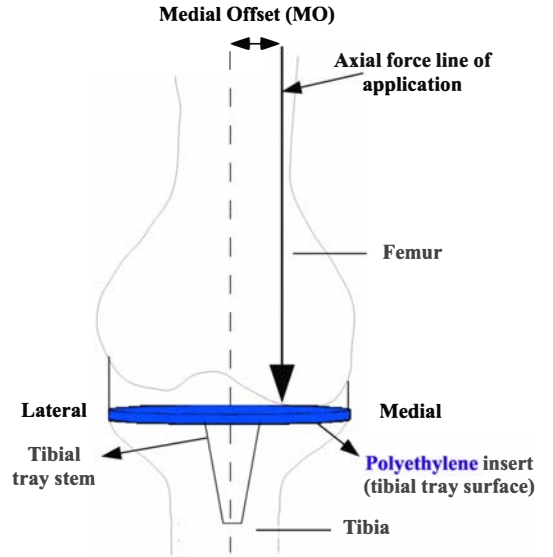


Fig. 2. The Medial Offset (MO) represents the displacement of the line of application of the axial force.

pressions for respective measurements are recalled here in (1) and (2):

$$COP_X = \frac{\sum_{i=1}^n F_i X_i}{\sum_{i=1}^n F_i} \quad (1)$$

$$COP_Y = \frac{\sum_{i=1}^n F_i Y_i}{\sum_{i=1}^n F_i} \quad (2)$$

where F_i can represent either the average force or the peak value component obtained over one gait cycle at the i^{th} force sensing device located at coordinates (X_i, Y_i) .

B. Measurements

A MTS 858 MINI BIONIX I knee simulator was used to emulate the knee motion. Four piezoelectric ceramic elements were placed in the four compartments of the tibial tray. Forces F_i were respectively measured in the form of proportionate voltages V_i . During *in-vitro* or *in-situ* experiments it is possible to emulate the ligaments behavior and calculate the collateral ligament tension [11] but that is not the case for *in-vivo* experiments or implanted prosthesis. Hence, the medial offset (MO) which is the displacement of the line of application of the axial force (Fig. 2), was used as an input to the knee simulator (ISO 14243) and COP values were calculated using (1) and (2). The results obtained for average and peak based fixed point COP calculations for different values of MO are shown in Fig. 3.

A strong correlation is obtained between the COP_X and the medial offset in the medio-lateral (ML) direction. This establishes the credibility of COP_X as a metric that can correctly represent the displacement of the line of application of the axial force on the tibial. As the observed dynamic range for COP_Y was not sufficiently large to effectively distinguish two different medial offset points, it is not considered here.

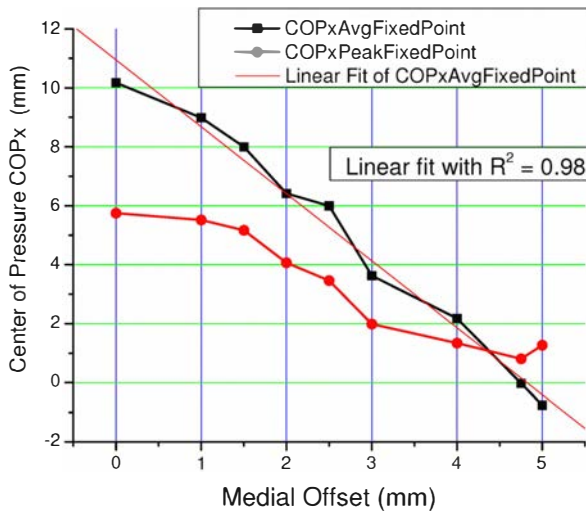


Fig. 3. Center of pressure displacement for average values of force components force components, with respect to the applied medial offset along the X axis.

C. Autonomous Measurement and Telemetry Architecture

A self-powered architecture conceived for COP measurement and transmission via an integrated telemetry system is shown in Fig. 4. The system is autonomous because the piezo ceramics, used to measure the axial force components, also generate power through piezoelectric effect. Power Harvesting Unit harvests this power and supplies to the rest of the system. The signal processing implements the logic to calculate the metric. It can be a digital circuit based data acquisition and processing system or the signals recovered from the piezo elements can be directly used to calculate the metric with the analog computation cells. The Clock Generation Unit (CGU) generates one or two different clocks depending on the digital or analog based systems. The Data Transmission Unit (DTU) transmits the data outside the body, to an external receiver and conforms to the Medical Implant Communication Service (MICS) standard working in 402-405 MHz frequency band. System and Power Management block takes care of system management. The feasibility study for such a system was done in [10]. In addition, COP can be calculated based on average or peak values, though they have considerable differences in terms of architectural efficiency. Both digital and analog based signal processing cores can be imagined, though area and power consumption may differ considerably. The expected power consumption of the system using a $0.35 \mu\text{m}$ CMOS fabrication process is 1.7 mW [12].

D. Discussion

It is clearly observed that the COP is a good read out for the collateral ligament imbalance metric as represented by the medial offset. Thus, COP values received via telemetry can be subsequently used to find the the medial offset using a linear fit analysis. The calculated medial offset versus the actual medial offset for fixed point implementation is shown in Fig. 5. A good correspondence is observed between the

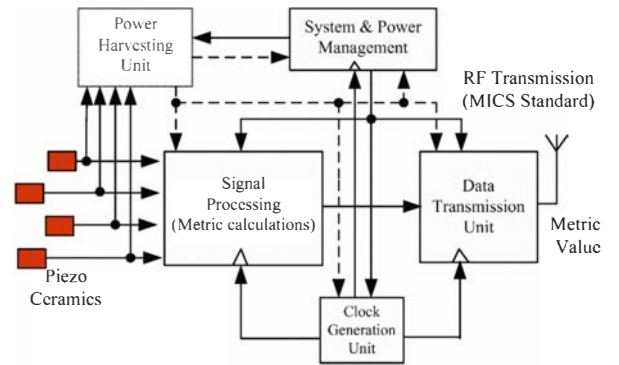


Fig. 4. An autonomous self-powered system architecture for ligament imbalance metrics calculation and their RF transmission [10].

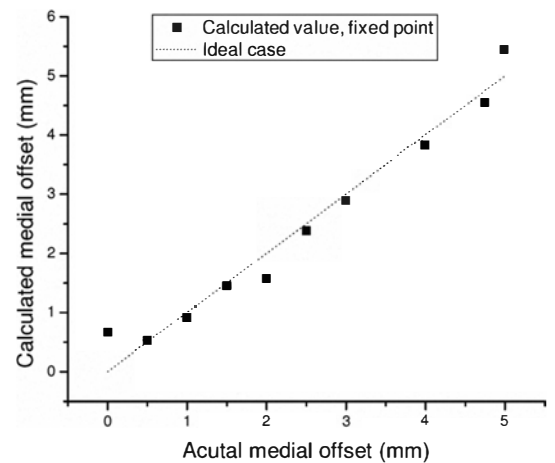


Fig. 5. Computed medial offset versus the applied (actual) medial offset. A good correspondence between them provides accurate measurement up to 1 mm precision.

actual and the calculated values. This medial offset represents the collateral ligament imbalance or ligament laxity as described earlier in [12]. Moreover, the COP value can be used to estimate and predict the PE wear and the life of the already implanted prosthesis as described in next section. The other advantage of the system *vis-à-vis* the state-of-the-art technique is in being self-powered and less cumbersome due to the removal of external induction coil used to power the implanted system [9].

IV. PERSPECTIVES

So far mostly *in-vitro* and *in-situ* techniques have been developed to monitor and estimate PE wear in knee prosthesis [1] [2]. Similarly few studies have been conducted to understand how parameters such as ligament laxity influences the joint kinematics post TKA [13] and its effect on polyethylene wear [3]. However, the principal drawback of these methods is, that they are applicable under *in-situ* scenario only and approximative, since it is not possible to exactly replicate the

knee joint motion. But in this work, the proposed approach goes a step ahead. After implanting the prosthesis with the system it would be possible to obtain real-time data under *in-vivo* conditions. Once the prosthesis is fitted with the system, via the medial offset metric, the ligament imbalance can be observed during different ambulatory activities such as walking, squatting etc.

Furthermore, fatigue test data correlating the PE wear and the number of cycles for different medial offsets can be observed using knee simulators [2]. In this way, a set of charts can be generated for PE component types with different shapes, materials and loading conditions. Consider a scenario in which a patient has been fitted with a knee prosthesis implanted with the proposed system. After a period of usage, during follow-up, a change in the metric value is observed i.e. medial offset is different from its previous position. This would be a clear indication that the position where the net axial force is applied on the tibial plateau surface has been displaced from its initial position. This implies a non-uniform tibial plateau surface and there is a PE wear at the site. Now, for the observed value of medial offset from the system, the fatigue test data can be referred for similar duration of usage (number of cycles) and for a similar type of prosthesis, an estimated volumetric loss of PE wear can be obtained. And by further extrapolating the data, the life of the implanted knee prosthesis can be predicted. In the long run, it might be possible to establish a relationship between the observed medial offset, the PE wear and ultimately the longevity of the prosthesis. It should be pointed out that COP calculations here do not take into account of dynamic parameters such as shear forces and torque. Though they don't make any significant part of total *in-vivo* forces exerted on tibial surface [8]. Using COP measurement, along with finite element analysis, it should be possible to calculate contact stresses which also influences the PE wear [2].

This technique can pave the way for an integrated measurement and monitoring system to evaluate ligament imbalance metric, PE wear and longevity for TKA operated knees. In such a system, an individual case can be monitored by calculating the imbalance metric under various physical activities. According to the observed data, the surgeon can recommend physical exercises which might aid in better adaptability of the prosthesis and a faster rehabilitation of the patient. This information could help prosthesis manufacturing houses to study and predict the implant longevity and subsequently improve their geometry and strength.

V. CONCLUSION

An approach for *in-vivo* estimation for polyethylene wear and the knee prosthesis longevity has been presented. The conceived method consists of utilization of an autonomous post TKA ligament imbalance measurement system and knee simulators, to provide an early assessment of the prosthesis state. Knee axial force components are measured to calculate their center of pressure, which also indicates

ligament imbalance. This metric, along with *in-situ* experiments, can be exploited to estimate the PE wear of the already implanted prosthesis and predict its potential life. Moreover, the information can be further used to ameliorate rehabilitation programs, establish relation between in-vivo forces and contact stresses and improve prosthesis design with better longevity.

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