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Original Article

Optimized Prototype of Instrumented Knee Implant: Experimental Validation

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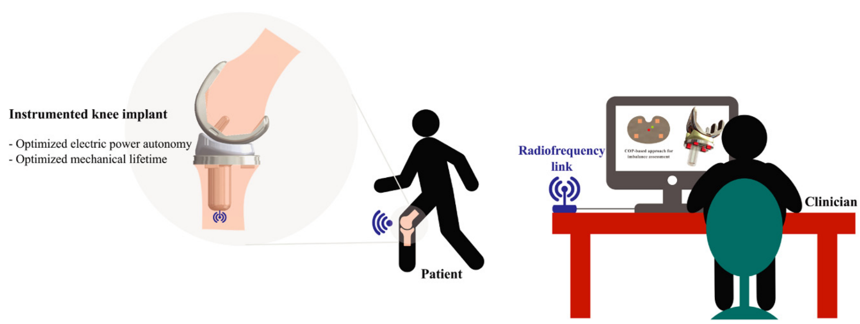
Graphical abstract



Abstract

Background: Embedding self-powered sensors into the knee implant for measuring *in-vivo* tibiofemoral force distribution can provide beneficial information to both clinicians and researchers. This information may help to reduce the risk of early failure after total knee arthroplasty. It can also be used to improve implant design, refine surgical techniques and enhance postoperative rehabilitation.

Methods: An experimental prototype of instrumented tibial baseplate has previously been proposed, developed and tested. A few shortcomings have been observed and identified during the experimental testing. In this study, the design of the proposed prototype was optimized to avoid the mechanical failure of the embedded piezoelectric generator/sensor. Furthermore, piezoceramics of greater height and smaller section were accommodated and tested in the optimized prototype to generate more electric power. This optimized prototype was also experimentally tested using a knee simulator to validate the optimization result.

Results: The optimization made to the experimental prototype allowed us to address the aforementioned shortcomings. The mechanical longevity of piezoceramics embedded into the optimized prototype was considerably enhanced with respect to the first prototype (optimized prototype: 54000 gait cycles, first prototype: a few cycles). The produced electric power was also increased (optimized prototype: 4.28 mW, first prototype: 1.81 mW).

Conclusion: The optimized prototype lasted for 54000 gait cycles without any obvious mechanical or electrical failures. The electric power produced in this prototype and quantified during experimental trials is sufficient to power an efficient low-power-consumption telemetry system.

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1. Introduction

In the field of orthopedic surgery, force sensors can be integrated within the implants in order to accurately measure the forces produced inside the prosthetic joints during daily life activities. The *in-vivo* measurement of intra-articular forces enables clinicians to better understand the postoperative evolution of implant loading conditions and their associated complications. As a result, the number of revision surgeries may be decreased. More specifically, the instrumentation of knee implant may enable clinicians to measure its lifetime in terms of walked steps. Knowing that the force cycle recorded throughout the full range of knee motion contains one major peak, the number of walked steps can be determined by counting the main peaks measured during the postoperative period prior to implant failure. The measured peak value may also help the patient to detect the activities that overload the implant. In this case, the patient must perform these activities less frequently than healthy people in order to avoid the early failure of knee implant. In addition, the instrumented implant may be used to provide the orthopedic device manufacturers with valuable information on the intra-articular loading during activities of daily life. This information is necessary for the improvement of implant design. The biofeedback based on force distribution information may also contribute to the rapid rehabilitation of prosthetic patients. In this case, the rehabilitation might be patient-specific based on the data provided by the instrumented tibial component. This is more appropriate than adopting the same rehabilitation protocol for every patient. Using this data, surgical techniques may also be refined in such a manner that the implant's function is enhanced and the implant's longevity is increased. Conceptually, the force data might be remotely collected without the need for clinical follow-up visits. This could decrease the cost of administering health care, and may allow the patient to be more closely monitored.

The sensors embedded within instrumented implants need to be powered during the *in-vivo* measurement of intra-articular forces. Therefore, they can be remotely powered by either electromagnetic induction [1–5] or through an integrated power harvester. For the implanted systems powered through inductive coupling, the reception coil is housed either into the stem of the metallic tibial component [1–3] or inside the polyethylene insert [4,5].

The major problem encountered when remotely powering instrumented knee implants using electromagnetic induction is the impossibility to stabilize the power transmission efficiency. This is due to the difficulty in satisfying a good tolerance in the misalignment between the internal and external induction coils [6] when the patient performs difficult activities such as ascending and descending stairs. During such activities, the position of external coil surrounding the patient's knee will continuously change relative to that of the internal coil. In this case, the misalignment tolerance cannot be maintained and consequently the power supplied to the implant may sometimes be insufficient to feed all the electronic components at same time. This may lead to measurement interruption and may accordingly involve repeating the same activity several times before acquiring a reliable measurement. In addition, the instrumented implants powered by induction will be less efficient during the more strenuous and athletic activities because of the movement restriction imposed by the existence of an induction coil around the patient's knee. Furthermore, having a coil around the knee will be neither practical nor comfortable for the prosthetic patient when performing daily life activities. On the other hand, when the secondary coil is placed inside the tibial component, eddy currents can be induced within the conductive metallic parts during remote powering. This may generate heat in the tissues surrounding the implant. This instance power loss may also decrease the transmission efficiency. Although embedding the secondary coil within the polyethylene insert may help to avoid efficiency-related problems, this may limit its usable lifespan due to possible induced wear. Therefore, fatigue endurance tests must be conducted on the instrumented polyethylene insert under the same conditions of *in-vivo* force measurement taking into account the six Degrees-of-Freedom (6-DOF) of knee motion during daily life activities in order to exclude this hypothesis.

In order to meet the need for *in-vivo* force-sensing in knee implants, we have proposed, developed, and tested an experimental prototype of self-powered instrumented tibial tray for monitoring tibiofemoral force distribution during daily life activities in the postoperative period [7–9]. Owing to the fact that the space available inside the tibial component to embed the electronics needed for force sensing is relatively small, piezoelectric elements have been used to cope with a twofold task. On one hand, these elements harvest the tibiofemoral forces produced inside the implant during knee motion and convert them to electric power [9]. The generated electric power is necessary to feed a low-power-consumption system supposed to be housed inside the implant stem for real-time data acquisition, processing and wireless transmission [8]. On the other hand, the piezoelectric elements monitor the changes in tibiofemoral force distribution that may occur postoperatively due to the morpho-functional evolution of patient, implant-specific factors or surgery-related factors. The initial force distribution among the piezoelectric elements embedded into the tibial baseplate can be determined via a Center of Pressure (COP) based approach [7]. The COP position is used to serve as a reference point for future comparisons. By periodically measuring the translation of the COP position with respect to the reference point, the postoperative instability of the implant in the MedioLateral (ML) and AnteroPosterior (AP) planes can accurately be assessed.

In this paper and based on our findings in previous work, we propose an optimized design of the tibial baseplate instrumented with self-powered sensor. This baseplate is custom-designed to house four piezoelectric elements. As in our previous work, these elements have a twofold task and can serve