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Material tailoring of the femoral component in a total knee replacement to reduce the problem of aseptic loosening

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ABSTRACT

Aseptic loosening of femoral components is a significant problem affecting the life of current total knee replacements. To help reduce the problem of aseptic loosening, a new metal–ceramic poros functionally graded biomaterial (FGBM) has been designed to replace the existing metal alloy material normally used. In order to investigate the effect of using a FGBM on distal femur stresses compared to using standard material in a femoral component, a three-dimensional finite element model of the knee prosthesis has been developed. The results of the modeling and subsequent analysis indicate that by using the new FGBM compared to the existing material in a femoral component, higher levels of stress can be realized in the adjacent bone area of the femur and as a consequence reduce harmful atrophy effects. Also, by a judicious choice of material combinations and variation of porosity in the FGBM, the surface properties can be tailored to improve wear resistance at the articular interface and bone anchorage at the femoral end, as well as varying the stiffness in the core of the femoral component. Therefore, the use of the new FGBM improves the performance of knee prostheses by addressing concurrently the three current leading causes of failure; stress-shielding of the bone by the implant, wear of the articular surfaces, and the development of soft tissue at the bone/prosthesis interface as a result of relative implant motion.

1. Introduction

The knee joint is one of the most complicated structures in the human body. It is made up of a combination of bony bodies (femur, tibia, patella and fibula), soft tissues (cartilages, menisci, ligaments, tendons) and synovial fluid. The knee is the strongest joint and supports almost the whole body weight and provides mobility. However, it commonly suffers from acute injury and development of osteoarthritis, which make the joint painful. Total knee replacements (TKR) are an efficient means of relieving extreme pain and restoring physical function in patients. In recent years, TKR has found critical importance in orthopedics as the statistical data has shown that the number of total knee arthroplasties by the end of 2030 is estimated to grow by 673% from the present rate, i.e. about 3.48 million procedures [1]. However, the success of today's TKRs is usually limited to a life span of around 10–15 years, which is a concern for younger and more active patients experiencing replacement surgery [2]. The revision procedure of a total knee implant is very expensive, causes pain for the patient, and the success rate is rather small compared to primary total knee arthroplasties [3]. Despite the unfavorable outcomes, the number of knee implant revision surgeries is predicted to increase by 601% between the years 2005 and 2030 [1]. Therefore, what is now needed is to reduce the rate of revision surgery by providing more durable knee prostheses.

One of the most serious problems related to revision surgery is aseptic loosening of TKR components [4,5]. Aseptic loosening occurs in all TKR components but in the femoral component is the most challenging problem. This is because it is the key component in a knee prosthesis, which articulates against the patellar and the tibial components and is attached to the distal end of femur and its failure can occur as a result of different causes. The femoral component, due to it interfacing with other components in the whole knee joint system, needs to optimize several specific functions to reduce or even prevent the incidence of aseptic loosening. This can be achieved by careful design and consideration of materials. Therefore, developing a new biomaterial for this component and/or modification of the existing design in order to meet the demand

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of optimal functions can help reduce the loosening problem and increase the life span of the implant. With this aim in mind, the paper evaluates and discusses the feasibility of tailoring a new functionally graded biomaterial (FGBM) specifically designed for a femoral component using finite element analysis (FEA).

2. Material design for femoral component

The use and development of materials have evolved from "materials by chance" to "materials by design" [6]. This evolution has had four stages of progression, as shown in Fig. 1, including "using the materials available on site", optimization of specific classes of materials, "hyper-choice of materials" and finally "tailored materials" or "materials by design strategies". The recent evolution emphasizes the importance of modeling and multi-functionality of materials. In different engineering fields, a large number of materials need to be specifically designed to meet the requirements for application specific and/or multi-functional materials [7]. The femoral component of a total knee replacement is a specific application that needs to perform multiple functions under different loading situations without failure (mainly due to the occurrence of aseptic loosening). Therefore, the design of a multi-functional material that is capable of fulfilling the particular requirements necessary to avoid loosening problem, will help provide longer lasting knee prostheses.

2.1. Design requirements

The knee prosthesis contains multiple components made of various materials in which all the components and their relative interactions influence the criteria for designing the components' materials. Therefore, determining the design requirements for a multi functional material to be used for a femoral component needs an overview of all TKR components and their respective positions in the knee joint system. Current TKRs are mainly composed of a femoral component, tibial tray, tibial insert and patellar component (Fig. 2). The femoral component replaces the distal end of femur and tends to mimic the natural shape of femoral condyles. The two condyles are highly polished and extend from the distal to posterior surface for the tibiofemoral articulation. This component also has a groove along the anterior surface for the patellofemoral joint. The tibial tray replaces the proximal end of tibia and provides a foundation for the tibial insert. Both, femoral component and tibial tray are usually made of metal alloys but sometimes fabricated from ceramics. The components can be fixed in place either with or without cement. The tibial insert, which articulates against the femoral component, distributes the load transferred from the femur to the tibia and has a low-friction surface with two slightly dished-out patches to match the condylar profile of the femoral component and to enable the required translations at the knee joint. The patellar component replaces the posterior part of the knee cap to articulate against the femoral component in the patellofemoral joint. This allows restoring the functions of the original patella i.e. protecting the front of the knee and increasing the moment arm for quadriceps muscles. The tibial insert and the patellar component are typically made of polymeric materials. Therefore, the articulating surfaces are metal-on-polymer interfaces.

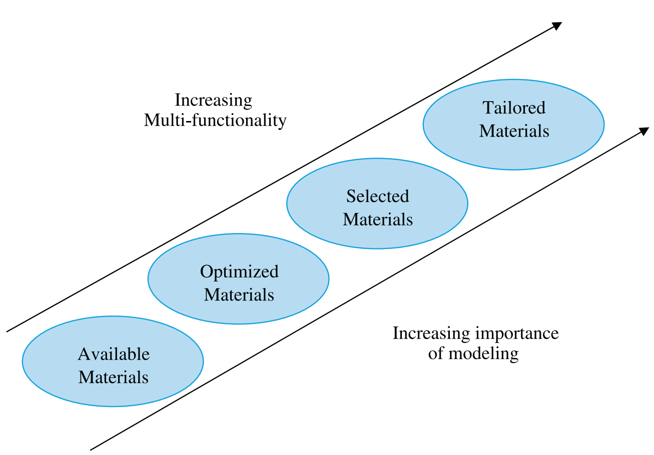

Fig. 1. Evolution in the use and development of materials [6].

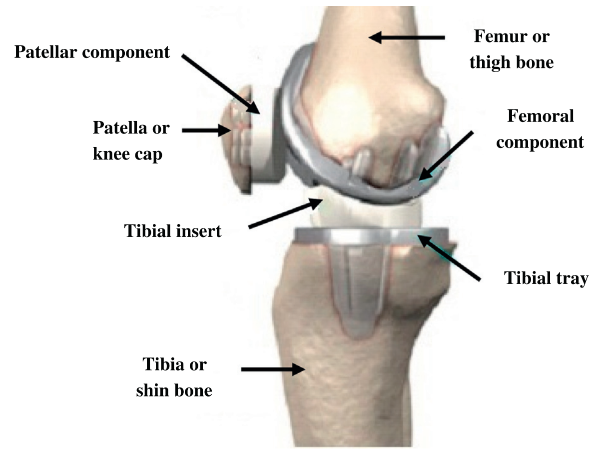

Fig. 2. The components of a total knee replacement.

When a failure occurs in an engineering product or system, the material, product design and the process require reconsideration because these aspects are related to each other and with the function and performance of the product. Usually, when a new material is designed or an existing material chosen to be used in a final product design, it establishes a specific design for manufacture approach in order to completely fulfill the desired requirements. It is reasonable that the design of a new material, in order to meet the demand for better performance, is accompanied with the design modification of product and vice versa. Generally, an amenable product innovation requires the engineering activities across materials, product design, and manufacturing to be more closely coupled. Fig. 3 shows the relation of parameters affecting the aseptic loosening and long term success of knee implants.

In total knee replacement, there exist three main leading causes for aseptic loosening:

(1) Excessive wear of articular surfaces.
(2) Stress shielding of the bone by implant, and
(3) Development of a soft tissue at the bone/prosthesis interface as a result of relative bone–implant micro-motion.

The femoral component in a TKR requires a biomaterial with properties to avoid the aseptic loosening problem as well as possessing good overall mechanical performance. These properties include high strength, low elastic modulus, good ductility, high corrosion and wear resistances, acceptable biocompatibility and good osseointegration capability [8]. An inability of the femoral component material to fulfill any one of these requirements or a combination thereof leads to failure of knee implants. A reduction in aseptic loosening is mostly influenced by having an elastic modulus close to that of bone, osseointegration ability (bioactivity) and high wear resistance. Materials currently used in femoral components have shortcomings in this regard. Therefore researchers have attempted to either develop new biomaterials or adapt existing materials. However, the majority of attempts at developing new