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On the influence of shape and material used for the femoral component pegs in knee prostheses for reducing the problem of aseptic loosening

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ABSTRACT

The integration of materials selection and design are essential to the success of new product development, especially when applied to biomedical devices. The knee prosthesis, like any other implant, is a product that still lacks satisfactory design solutions for solving the problem of aseptic loosening. Stress shielding is one of the main causes of aseptic loosening that is intimately related to the overall design of the knee prosthesis. The design of the location pegs in the femoral component of the knee prosthesis is seen to have a critical effect on the stress shielding. In this study, therefore, different combinations of location peg geometries and material designs were assessed using finite element analyses in conjunction with a design of experiments procedure. The materials considered were Co–Cr alloy (as reference material) and functionally graded material (FGM) for the main body of the femoral component, and various porous materials for the pegs (as promising new materials). The performance outputs (responses) were stress levels in the femoral bone to assess the stress shielding effect, and stress levels in the pegs to assess adequate peg strength. The result revealed conflicts in satisfying the design objectives. Therefore, a multi-objective optimization was carried out to find the optimal geometries of the pegs for the femoral component. Based on the findings of the optimization process, a set of candidate designs was generated and a multi-criteria decision making approach used to obtain the final ranking of candidate designs. The ranking order demonstrated the superiority of using a FGM femoral component with porous material pegs of conical geometry. By comparing the results with the standard Co–Cr design, it was shown that the new design of pegs can significantly increase the magnitude of stresses seen at the distal femur; hence reduce the stress shielding effect, without over compromising on the strength of the pegs.

1. Introduction

One of the major complications after total knee replacement (TKR) is aseptic loosening of the implant components, which commonly ends up with a revision surgery. Stress shielding is one of the main causes of aseptic loosening, leading to bone loss, lack of post-operative implant stability and migration of implant due to the progressive failure of the supporting cancellous bone [1]. In particular, when stress shielding is caused by the femoral component, it may bring about condylar osteoporosis, periprosthetic fractures of the femur, and successive failure of the femoral component [2]. There is frequent clinical evidence [3–7] that stress shielding is closely associated with the use of the knee prosthesis components. Several research studies have been conducted in this area and various knee designs have been evaluated. Saari et al. [3] investigated the effect of different geometrical designs of the knee tibial insert, with preserved and sacrificed posterior cruciate ligament, on femoral bone loss after TKR (5-year follow-up) and found that the posterior stabilized component increases the bone loss. Seki et al. [4] evaluated changes in bone mineral density (BMD) in the distal region of femur two years after TKR with three non-cemented different femoral components' interface geometry and a cemented femoral component. They identified various amounts of bone loss for different designs, with the most decrease found around the cemented component.

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One of the interfacing features that plays an important role in the effectiveness of primary and revision knee prostheses is the peg or stem. The functions of pegs and stems are to provide additional fixation, ensure appropriate alignment of the components, and moreover, help to transfer the load to the adjacent cancellous bone [1,5–7]. Petersen et al. [8] quantified the changes in BMD of the distal femur caused by a non-cemented porous-coated femoral component with peg fixation. They found an increase of 22% in BMD, two years after TKR, in the proximal region of the femoral pegs. Furthermore, Shi et al. [1] studied the stress shielding in the distal femur by simulating a dynamic model and observed higher stress levels in the bone adjoining to the femoral component pegs. Meanwhile, it is well indicated in the literature that the design of peg or stem, including geometry and material, influences the stress shielding [5–7,9,10] and these considerations play an important role in the success rate of the TKR. Since there is close correlation between the material used and the desired functions of a system, the selection or design of a material should be integrated with the geometrical design where the material is applied. Therefore, material design and geometry design should be integrated [11]. To the best of the authors' knowledge there exists no investigations regarding the effect of peg geometry on the stress shielding with respect to the materials used. Recently, there has been an increasing trend in the use of functionally graded materials for biomedical applications [12–14]. Several studies have been conducted on the potential of ceramic–metal FGM for being used in the main body of the femoral component and on the use of porous material for the pegs in total knee prosthesis [15–17]. Although the emphasis of these studies has been on the multi-functionality of the implant materials to be able to reduce the stress shielding, wear and micro-motion (as primary causes of aseptic loosening) simultaneously, the effect of geometry was not considered. In this regard, the current study aimed at evaluating the design aspect for this suggested material and standard Co–Cr alloy.

Design of experiments (DOE) approach is used as a systematic strategy that can efficiently identify the main design variables and the possible interactions of the variables that are believed to be linked to the functional performance. The multi-criteria design approach is also used to address the conflicts between the design objectives towards finding the best solution for reducing the aseptic loosening problem.

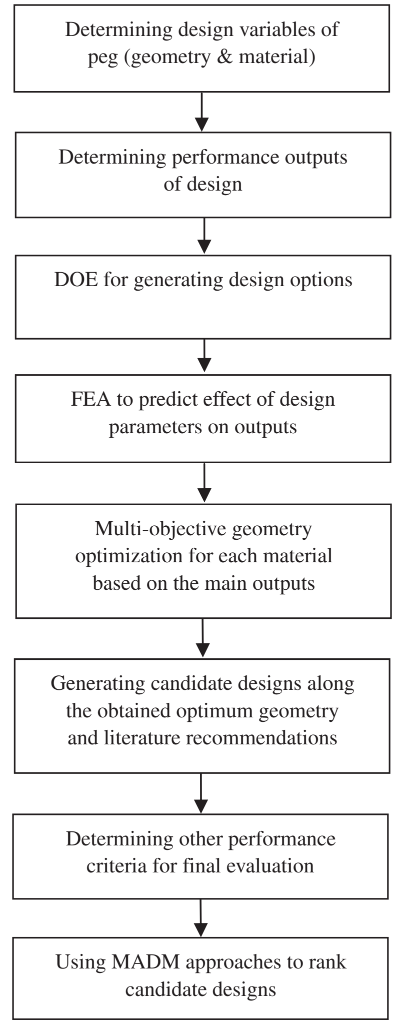

Fig. 1. The steps used in the design methodology.

2. Materials and method

The methodology used in the research described in this paper consists of three main steps (Fig. 1); (1) using combination of DOE and finite element analysis (FEA) to analyze the interactions, and to identify the direction of improvement in goals with respect to design variables, (2) finding the primary optimized geometry of peg for each material through multi-objective optimization in Design-Expert [18] computer program, and (3) creating a database of promising designs and selecting the final design using multi-attribute decision making (MADM) approach.

2.1. Planning of computational experiments

To design an experiment means to pick the optimal experimental design to be used for varying all the factors being analyzed concurrently. By designing an experiment more precise data and more complete information on a studied fact can be attained through a minimal number of experiments. The development of statistical approaches for data analysis, in combination with advances in computer technology, has modernized research and development in all fields. Various methods are used in DOE for process improvement and design optimization. For adequate optimization, the main, quadratic and interaction terms are to be determined and response surface methodology (RSM) must be established. RSM is an efficient optimization approach used to accomplish the multi-objective optimization procedure. Therefore, a central composite rotatable experimental design (CCRD) was employed in this study to plan the computational experiments (runs) of peg design optimization and RSM was used to find the relationships between the peg design parameters and the responses. Subsequently, the optimization capabilities in Design-Expert software were utilized to perform the multi-objective optimization of the peg design. Three variables were selected, including peg length (L) and peg diameter (D) as two numerical factors, and femoral component/peg material as a categorical factor. Three responses were also considered, including weighted mean and standard deviation (STDV) of stresses within the femur, and mean stress at pegs. The CCRD used in the current study consisted of two combinations of 9 design points, as shown in Fig. 2, leading to 18 experiments. Since the finite element experiments contained no actual experimental error, replication of the center point was not necessary and therefore a single center point was considered adequate. The ranges and levels of variables investigated in this study are shown in Table 1.

2.2. Finite element model

FEA was carried out for two sets of designs; 18 models based on CCRD and 12 models based on the optimized geometry of peg. The