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Technical note

Above-knee prosthesis design based on fatigue life using finite element method and design of experiment

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ABSTRACT

The main objective of this work is to improve the standard of the existing design of knee prosthesis developed by Thailand's Prostheses Foundation of Her Royal Highness The Princess Mother. The experimental structural tests, based on the ISO 10328, of the existing design showed that a few components failed due to fatigue under normal cyclic loading below the required number of cycles. The finite element (FE) simulations of structural tests on the knee prosthesis were carried out. Fatigue life predictions of knee component materials were modeled based on the Morrow's approach. The fatigue life prediction based on the FE model result was validated with the corresponding structural test and the results agreed well. The new designs of the failed components were studied using the design of experimental approach and finite element analysis of the ISO 10328 structural test of knee prostheses under two separated loading cases. Under ultimate loading, knee prosthesis peak von Mises stress must be less than the yield strength of knee component's material and the total knee deflection must be lower than 2.5 mm. The fatigue life prediction of all knee components must be higher than 3,000,000 cycles under normal cyclic loading. The design parameters are the thickness of joint bars, the diameter of lower connector and the thickness of absorber-stopper. The optimized knee prosthesis design meeting all the requirements was recommended. Experimental ISO 10328 structural test of the fabricated knee prosthesis based on the optimized design confirmed the finite element prediction.

1. Introduction

Currently, there are more than 50,000 amputees in Thailand. The main causes are 45% road-related accidents, 25% landmine accidents, 20% chronic diabetes and 10% of other causes. The cost of total leg prosthesis system for Thai amputee is high due to the high cost of knee prosthesis. The Prostheses Foundation of Her Royal Highness the Princess Mother has been producing and giving prostheses to disabled people, in Thailand and other South-East Asian countries, in need of replacement limbs since 1992. The study of Thailand's Prostheses Foundation OPD cards showed that the knee prostheses often need repairing after 2 years of using. The main cause was fatigue and wear of the knee component parts. Moreover, the polycentric knee prosthesis developed by the Foundation does not meet the ISO-10328 [1] structural standard test for a knee prosthesis.

The type of prosthetic knee used depends on the amputee's strength and activity level. There are three types of knee mechanisms, which are side bars with joints, single-axis knee prosthesis and polycentric knee prosthesis [2,3]. Polycentric knee prostheses are more stable and easier to control during swing and stance phase, but are more expensive. A polycentric knee mechanism is a two-six bar linkage joint. Several researches of polycentric knee prostheses involve the study of their dynamic stability [4–6]. The optimization of knee prosthesis based on structural strength by varying design parameters has not been explored. Finite element (FE) analyses are commonly used to investigate the fatigue strength and wear resistance of knee implants since FE modeling allows easy parametric study without the need to manufacture knee implants [7–9]. An FE model-based topology optimization of knee prosthesis is reported to lower its weight while successfully increase its strength [10]. The full factorial design of experiment or Taguchi method is suitable for parametric study of complex mechanisms such as monolimb [11,12] since there is interaction between the design parameters. This work aims to study the failure of knee prosthesis under the structural test and to develop an optimum design of knee prosthesis to meet the require-

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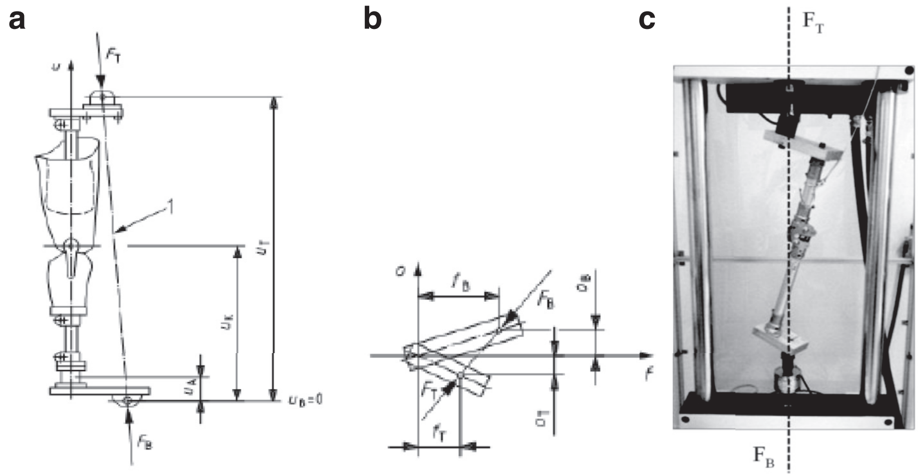

Fig. 1. (a, b) alignment setting conditions according to ISO 10328 [1], (c) The structural testing machine.

Table 1
Mechanical properties of knee prosthesis materials [14–17].

Material /Properties	Density (g/cc)	Young's modulus (GPa)	Yield stress (MPa)	Poisson's ratio	Ultimate stress (MPa)
1. Aluminum ADC 12	2.823	71.0	144.35	0.33	205.31
2. SUS 304	8.00	200	250	0.29	505
3. SUS 630 (H900)	7.80	196	1034	0.272	1241
4. Ester Polyurethane (PU)	1.2	0.0689	56	0.4	56

ments of ISO 10328:2006 under static and cyclic tests. This paper applies finite element analysis and design of experiment to study and optimize the design parameters of a knee prosthesis in order to increase its fatigue life.

2. Methods

2.1. Structural testing of knee prosthesis

The ISO 10328:2006 structural testing of the knee prosthesis specifies forces for 3 amputee's weight levels at normal walking phase (cyclic loading) and severe ultimate load during heel-strike (condition I) and toe-off (condition II). The alignment is defined in the ISO 10328 by the distances F, O and U in X, Y and Z directions at three reference planes on the total limb replacement, i.e. hip level, knee level, foot level, as shown in Fig. 1. This illustrates the walking motion during heel-strike (condition I) and toe-off (condition II) [10]. The ISO 10328 requires knee prostheses to undergo 3,000,000 cyclic loading and static ultimate loading without failure to any knee components and a combined knee deflection of less than 5 mm. The alignment and forces used in this knee prosthesis structural testing are according to P4 (80 kg) condition I. The structural testing took place at the Sirindhorn National Medical Rehabilitation Centre, Thailand, using a 5 kN servo-pneumatic fatigue testing machine by Si-Plan Electronics Research Ltd (Fig. 1(c)). The cyclic loading was 1230 N at speed of 1 Hz. The knee testing is set up by using two Aluminum tubes and top and bottom plate fixtures to tie all components together (Fig. 1). The lengths of fixture tubes are 150 mm and 500 mm for top and bottom parts, respectively. At the top plate, F_T is 89 mm. and O_T is −74 mm. At knee level, Fk is 56 mm. and Ok is −48 mm. Fb and Ob is −52 mm. and 39 mm. respectively at the lower (foot) plane.

2.2. Finite element analysis

The polycentric knee prothesis,designed by the Prostheses Foundation, is a four-bar linkage knee joint with a hydraulic swing phase control as shown in Fig. 2(a). The knee prosthesis components consist of cover joint bar, knee joint upper, stopper, joint bar, roller pin A upper and lower, roller pin B, knee joint lower and friction pin C. Total weight of a knee joint is 500 g. Materials of knee component are stainless Steel SUS 304 and SUS 630, Aluminum ADC 12 and Polyurethane. Two bearings were used in roller pin assembly of the knee prosthesis and the other connections were shirk-fitted and glued together.

The CAD geometry of the knee prosthesis is shown in Fig. 2(b). A 3D finite element mesh of the knee prosthesis and testing fixtures was created using ABAQUS auto-mesh option. All simple parts were meshed with 3D-C3D8R elements, while all complex parts were meshed with 3D-C3D4 elements [13]. The testing fixtures were assumed rigid. The number of elements range from 1640 elements for roller pin to 53,268 elements for upper knee joint part. The elastic-plastic material model was applied for all materials. The Young's modulus, Poisson's ratio, density, yield and ultimate strength of all materials are shown in Table 1. Contact pairs between pins, upper, lower and joint bars, where bearings were used and sliding allowed, were modeled with friction contact with the friction coefficient of 0.1. Tie constraints were applied to glued and shirk-fitted assembly pairs. All connections between knee prosthesis and testing fixture were assumed tied together and no movements were allowed. Cyclic loading of 1230 N was applied at the top loading fixture. The point of loading at the bottom plate was fixed. The alignment of knee testing model resembled that of the ISO 10328 experimental knee test under P4 and condition I as shown in Fig. 2(c).

2.3. Fatigue life prediction

Fatigue life prediction of knee prosthesis components are based on the Morrow's Approach [18].The equation is as follows:

$$\frac{\sigma_a}{\sigma_f} = \left(2N_f\right)^b \tag{1}$$