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A robust design procedure for improvement of quality of lower-limb prosthesis

Nian-Zhong Chen
The Hong Kong Polytechnic University

Winson Lee
University of Wollongong, ccwlee@uow.edu.au

Ming Zhang
The Hong Kong Polytechnic University

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Abstract

Lower-limb prostheses are used to restore amputee's walking. Monolimb is one of the designs referring to socket and the shank being molded into one piece of thermoplastic material. Appropriate shank flexibility of a monolimb can improve gait of an amputee. However, during the fabrication, the variations of design variables are inevitably produced which may lead the unexpected shank deflection and directly influence on gait efficiency of an amputee. This paper presents a robust design procedure for improvement of quality of the monolimb by simultaneously minimizing performance variations caused by variations in design variables and bringing the mean value of performance on target. The robust design procedure embodies the integration of response surface methodology with genetic algorithms. Response surface models are developed for the responses of monolimb as functions of design variables over the region of interest and genetic algorithms are employed to find the robust solution. A robust design of monolimb is performed for an amputee subject and the results show that the robust design can design a "robust" monolimb which provides specified performance targets that are minimally sensitive to the variations of design variables. This indicates that robust design may have the potential application in improving the quality of the prescribed prosthesis.

Keywords

robust, prosthesis, procedure, lower-limb, quality, design, improvement

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A robust design procedure for improvement of quality of lower-limb prosthesis

Nian-Zhong Chen, Winson C.C. Lee and Ming Zhang *
Department of Health Technology and Informatics, The Hong Kong Polytechnic University, Hong Kong, P.R. China

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Abstract. Lower-limb prostheses are used to restore amputee's walking. Monolimb is one of the designs referring to socket and the shank being molded into one piece of thermoplastic material. Appropriate shank flexibility of a monolimb can improve gait of an amputee. However, during the fabrication, the variations of design variables are inevitably produced which may lead the unexpected shank deflection and directly influence on gait efficiency of an amputee. This paper presents a robust design procedure for improvement of quality of the monolimb by simultaneously minimizing performance variations caused by variations in design variables and bringing the mean value of performance on target. The robust design procedure embodies the integration of response surface methodology with genetic algorithms. Response surface models are developed for the responses of monolimb as functions of design variables over the region of interest and genetic algorithms are employed to find the robust solution. A robust design of monolimb is performed for an amputee subject and the results show that the robust design can design a "robust" monolimb which provides specified performance targets that are minimally sensitive to the variations of design variables. This indicates that robust design may have the potential application in improving the quality of the prescribed prosthesis.

Keywords: Lower-limb prosthesis, monolimb, robust design, finite element analysis, response surface methodology, genetic algorithms

1. Introduction

Thermoplastics have been growing in use in the field of lower-limb prosthetics. One kind of transtibial prosthesis has been fabricated with the prosthetic socket and the shank being molded into one piece of thermoplastic material. It is often called as monolimb [1] though some other names were used such as endoflex [2], total thermoplastic prosthesis [3] and ultra-light prosthesis [4,5]. Monolimb can be designed to have more flexibility than the modular prostheses. By proper structural design using appropriate geometry of the shank and thickness of the thermoplastic material, the shank can deform leading to simulated dorsiflexion and plantarflexion of the prosthetic foot, which might improve gait and comfort of an amputee [6].

During the design stage of monolimb, attention is usually paid to giving suitable deflection of the shank and simultaneously ensuring endurance strength. Up to now, there is no guideline for the shank

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*Corresponding author: Ming Zhang (PhD), Department of Health Technology and Informatics, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong, P.R. China. Tel.: +852 27664939; Fax: +852 23624365; E-mail: htmzhang@polyu.edu.hk.

design to give proper flexibility while maintaining enough fatigue life under normal uses. Appropriate dimensions and thicknesses of the material of a monolimb for different amputees are desired. It should be noted that during the fabrication of monolimbs, especially manually fabricated, the dimension and thickness of the shank may not be exactly what the designers specified. These variations may be due to poor thermoforming and over-stretching of the thermoplastics. This can lead to unexpected shank deflection and directly influence gait efficiency of an amputee. In order to avoid the instability of shank deflection caused by fabrication technology and ensure the quality of monolimb, it is desired to let prescribed shank deflection be minimally sensitive to the variations of design variables.

Robust design is an engineering method for optimizing the product and process conditions which are minimally sensitive to the various causes of variation. The typical applications of robust design are the Taguchi's approaches [7] where basically a two part orthogonal array is used for experimental design using the signal-to-ratio as an optimization criterion. Chen et al. [8] proposed a robust design method, which integrates the response surface methodology with the compromise decision support problem, for the design of a solar powered irrigation system. Their work indicates that the method, which combines response surface methodology with optimization methods, is useful to the problem where system performances are the implicit functions of design variables.

In principal, robust design is an optimization problem. Ramakrishnan and Rao [9] formulated the robust design problem as a nonlinear optimization problem with Taguchi's loss function as the objective. Sundaresan et al. [10] incorporated a sensitivity index in the optimization procedure to determine a "robust optimum". However, their optimization methods often encounter different difficulties of problem, such as gradients, Hessians, linearity and continuity, etc. To overcome these difficulties, genetic algorithms is a choice since they have been verified to be able to overcome those problems [11–13].

In the paper, a robust design procedure is presented to design a "robust" monolimb for a 55 year-old right-sided transtibial amputee subject. The objective of the robust design is to design a monolimb with an expected fatigue life while keeping a prescribed dorsiflexion angle which is minimally sensitive to the variations of design variables.

2. Method

2.1. Finite element analysis

Finite element (FE) analysis was performed to simulate the amputee subject of 55 year-old and 81 kg in body mass walking with monolimbs of different designs. Figure 1 shows the geometries of the FE model. The geometry of bones and their relative positions to the skin surface were obtained from magnetic resonance imaging processed using Mimics 7.1. Monolimb was designed using ShapeMaker$^{\text{TM}}$ 4.3. A prosthetic foot, partitioned into keel and surrounding rubber foam, was created in SolidWorks$^{\text{TM}}$ 2001 and was connected to the distal end of the shank. Details of the geometry preparation were described in [1].

Young's modulus and Poisson's ratios are assigned to the FE model according to the literature resembling the material property of soft tissue, polypropylene homopolymer, prosthetic keel and surrounding rubber foam (Table 1). Bones were given fixed boundary conditions, and loading was added at the plantar surface of the prosthetic foot according to the gait analysis data using force platform and Vicon Motion Analysis System. Contact between the limb and the socket was simulated considering friction/slip using automated contact technique described in [14].

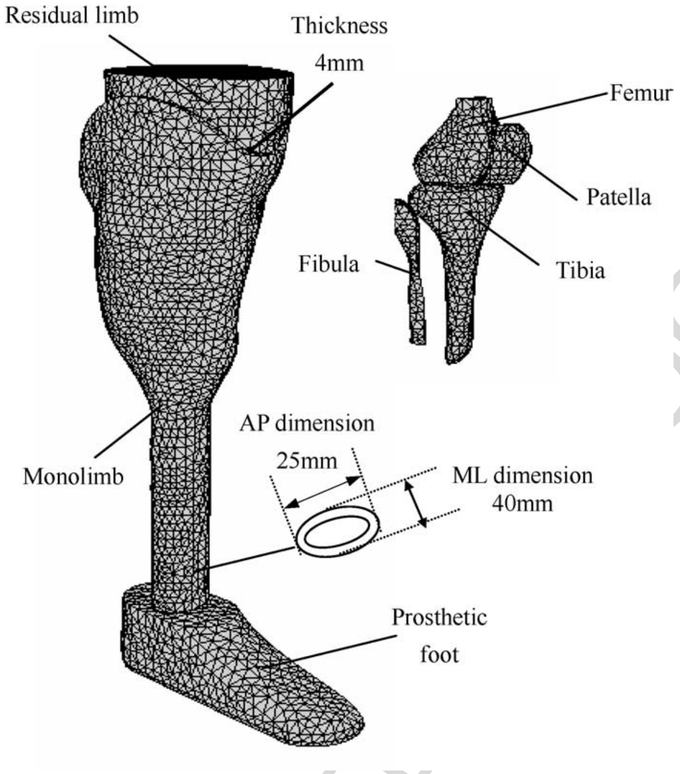

Fig. 1. Finite element model and design variables of monolimb used in the robust design.

Table 1
Material properties assigned in the finite element model

Item	Young's modulus	Poisson's ratio
Soft tissue	200 kPa	0.45
Bones	As fixed boundaries	
Keel	700 MPa	0.3
Rubber foam of prosthetic foot	5 MPa	0.3
Socket	2500 MPa	0.3

2.2. *Maximum dorsiflexion angle of monolimb*

The "dorsiflexion angle" is defined in this paper as the angle changes between the transverse plane and the flat surface of the prosthetic foot attached to the shank after external loadings are added. The "foot dorsiflexion angle" takes into account the motions of the prosthetic foot due to deformation of the shank and the movement of the whole monolimb with respect to the residual limb.

In order to find the maximum dorsiflexion angle of monolimb during stance phase of the gait cycle at normal walking, a monolimb with the thickness of 4 mm, antero-posterior and medial-lateral dimensions of the shank 25 and 40 mm is analyzed using finite element analysis. The results of the dorsiflexion angle of the monolimb during stance phase of the gait cycle are shown as Fig. 2. It is seen from Fig. 2 that the maximum dorsiflexion angle of monolimb is at terminal stance (45.1% of gait cycle). Therefore, the dorsiflexion angle at 45.1% of gait cycle is regarded as the maximum dorsiflexion angle in the paper.

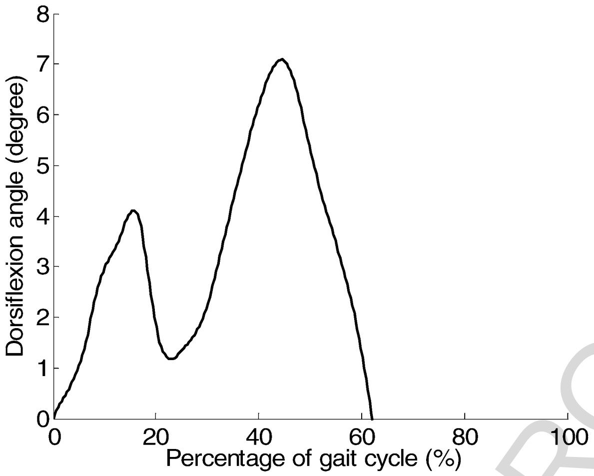

Fig. 2. Dorsiflexion angle of the monolimb during stance phase of the gait cycle.

Table 2

Loadings and responses in the finite element model of the monolimb with thickness of the thermoplastic material 4 mm, anteroposterior and medial-lateral dimensions of the shank 25 and 40 mm

Percentage of gait cycle	Ground reaction forces (N)			Position at the shank with the maximum principal stress	Maximum principal stress value (MPa)
	Anteroposterior	Medialateral	Vertical		
4.2	46.2	−13.7	132.9	Postero-proximal	1.6
5.6	60.6	−11.2	192.8	Postero-proximal	2.1
7.0	81.6	−19.11	329.3	Postero-proximal	3.1
8.5	98.8	−9.7	474.4	Postero-proximal	4.8
12.7	65.8	61.4	747.1	Postero-proximal	7.7
15.5	13	64	936.7	Postero-proximal	8.7
16.9	−23.5	63.6	979.7	Postero-proximal	12.5
19.7	−69.5	71.2	897.7	Postero-distal	11.3
25.4	−52.9	51.7	599.5	Postero-distal	8.4
29.6	−40.2	43.7	515.5	Postero-distal	8.6
32.4	−38.4	45.2	569.4	Postero-distal	11.5
35.2	−72.6	58.5	646.3	Postero-distal	15.8
42.3	−74.2	65	802.2	Postero-distal	21.4
45.1	−75.8	68.7	772.5	Postero-distal	21.8
49.3	−76.8	61.1	595.1	Postero-distal	17.3
52.1	−58.1	35.8	397.3	Postero-distal	14.0

2.3. Evaluation of Fatigue life

Based on the finite element analysis simulating the amputee subject walking for a gait cycle (Table 2), it was found that maximum principle stress was peaked over the postero-distal end of the shank (Fig. 3) at terminal stance (45.1% of gait cycle). This suggests that fatigue failure would most likely happen over this region.

During normal walking, the monolimb is subjected to the cycle load and the periodical stress is applied to the monolimb. The Miner's rule [15] which is suitable to predict the fatigue life of a structure subjected

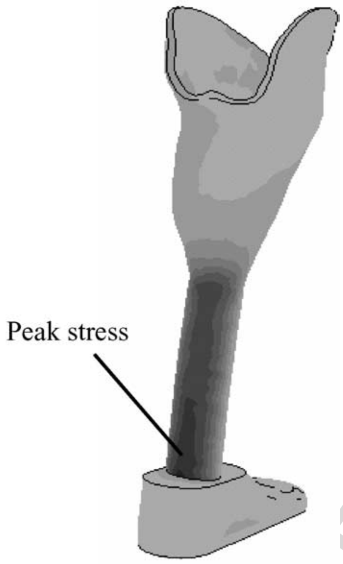

Fig. 3. Maximum principal stress distribution in the finite element model of monolimb at 45.1% of gait cycle.

to the cyclic load is used to determine the fatigue life of monolimb according to the maximum principal stress of shank at the postero-distal end of the shank. The Miner's rule is defined as

$$\sum \frac{n_i}{N_i} = 1, \tag{1}$$

where n_i is the number of cycles at the ith specified stress S_i; N_i the fatigue life (number of cycles to failure) of material at the ith specified stress S_i.

After performing finite element analysis for the monolimb with the thickness of the thermoplastic material 4 mm, antero-posterior and medial-lateral dimensions of the shank 25 and 40 mm, the maximum principal stress at the postero-distal end of the shank of the monolimb during stance phase of the gait cycle is shown as Fig. 4. Figure 4 shows two peaks of maximum principal stress during the stance phase of gait cycle, S_1 at 16.9% of gait cycle and S_2 at 45.1% of gait cycle. So the Miner's rule for monolimb is reformulated as

$$\frac{n}{N_1} + \frac{n}{N_2} = 1, \tag{2}$$

where n is fatigue life of monolimb (the maximum number of walking steps); N_i the fatigue life of monolimb at the ith specified stress S_i.

In order to compute the N_1 and N_2, Wirsching S–N curve model [16] is used here

$$NS^m = K, \tag{3}$$

where m is fatigue strength exponent; K fatigue strength coefficient; N fatigue life of material under stress S. Then, the N_1 and N_2 are easily obtained from the Eq. (3) according to S_1 and S_2.

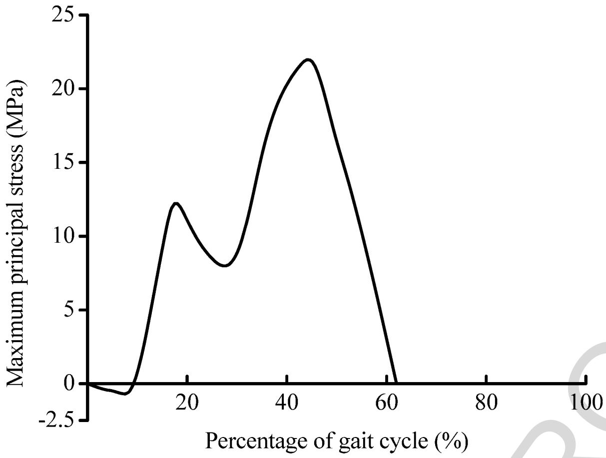

Fig. 4. Maximum principal stress at the postero-distal end of the shank during stance phase of the gait cycle.

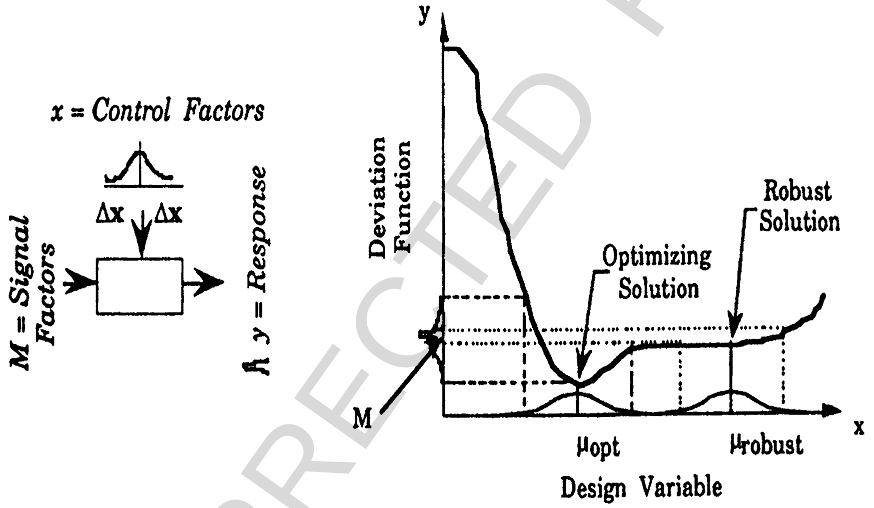

Fig. 5. A schematic of the concept behind robust design [8].

2.4. Concept of robust design

The concept of robust design applications is illustrated in Fig. 5. On the left-hand side of Fig. 5, the P-diagram [8] is used to represent parameters and their relationships with the whole system. Control factors (x) are parameters that can be specified freely by a designer and signal factors (M) are the intended values for the response (y) of a product/process. The variation in response is caused by variations in control factors.

On the right-hand side of Fig. 5, a schematic of the concept of robust design is presented. Performance is a function of only one variable, x. To reduce the variation of response caused by variations of design variables, instead of seeking the optimum value $x = \mu_{\text{opt}}$, a robust designer is interested in identifying the flat part of a curve near performance target and the robust solution $x = \mu_{\text{robust}}$ is a better choice. Because design variables vary within the region $\pm\Delta x$ of their means, the resulting variation of response of the design at $x = \mu_{\text{robust}}$ is much smaller than that at $x = \mu_{\text{opt}}$, while the means of the response at two designs are close.

2.5. Robust design of monolimb

The robust design in the paper is to design a "robust" monolimb for the 55 year-old right-sided transtibial amputee subject. The design is to determine a monolimb providing fatigue life of monolimb more than one million cycles under normal walking while keeping a stable maximum dorsiflexion angle at 8 degrees which is minimally sensitive to the variations of design variables.

Three design variables are considered in the robust design: thickness of the thermoplastic material (x_1), antero-posterior dimension (x_2) and medial-lateral dimension (x_3) (Fig. 1). x_1 is set in the range of 4–6 mm. x_2 and x_3 are in the range of 25–40 mm. Two response outputs are yielded: the maximum dorsiflexion angle and the maximum principal stress of the monolimb. Loading is applied at the plantar surface of the prosthetic foot at 16.9% and 45.1% of the gait cycle according to our gait analysis data [17]. x_1, x_2 and x_3 are assumed to be subjected to normal distribution and the coefficients of deviation of them are given by 0.15, 0.1 and 0.1, respectively.

The robust design is composed of three major steps.

In step 1, response surface models are built to relate each response of monolimb to the design variables using response surface methodology [18]. A second order model, which has linear terms, quadratic terms and interaction terms, is used here

$$\hat{y} = f(\mathbf{x}) = \psi_0 + \sum_i \psi_i x_i + \sum_i \psi_{ii} x_i^2 + \sum_i \sum_{j>i} \psi_{ij} x_i x_j, \tag{4}$$

where $\hat{y}$ is the estimated response; $\mathbf{x}$ the vector of design variables; x_i the design variable i; ψ_0, ψ_{ii}, and ψ_{ij} the regression coefficients of the model.

In step 2, the mean value and variance of the two responses are derived from the response surface models. According to the first-order Taylor expansion, the mean value of response $\mu_{\hat{y}}$ and the variance of response $\sigma_{\hat{y}}^2$ are expressed as

$$\mu_{\hat{y}} = f(\mu_{\mathbf{x}}), \tag{5}$$

$$\sigma_{\hat{y}}^2 = \sum_i \left(\frac{\partial f}{\partial x_i} \right)^2 \sigma_{x_i}^2, \tag{6}$$

where μ represents the mean value and σ the standard deviation.

In step 3, the robust solution is achieved by genetic algorithms through minimizing the variance Eq. (6) and by binging the mean value Eq. (5) to the target. The fundamental principal of genetic algorithms is to search the solution space of a function through the use of the survival of fittest strategy. The fittest individuals of any population tend to reproduce and survive to the next generation, thus improving successive generations. Details of the genetic algorithms can be found in Refs [11–13].

In this robust design, the general objective can be divided into a sub goal and two constraints.

The sub goal is to minimize the variance of the maximum dorsiflexion angle of monolimb (*VMDG*). This goal can be gained by maximizing the normalized *VMDG* (*NVMDG*), which is defined as

$$\mathit{NVMDG} = \frac{\mathit{VMDG}_{\max} - \mathit{VMDG}}{\mathit{VMDG}_{\max} - \mathit{VMDG}_{\min}}, \tag{7}$$

where $VMDG_{\max}$ and $VMDG_{\min}$ are the maximum and minimum of the *VMDG*, respectively.

The two constraints are that the mean value of the maximum dorsiflexion angle (*MDG*) must be kept at 8 degree and the fatigue life of monolimb (n) must be more than one million cycles. They can be satisfied by maximizing the values of two penalty functions *PFMDG* and *PFN* that are defined as

$$PFMDG = \begin{cases} 0 & \text{if abs}(MDG - 8) \leqslant 1 \times 10^{-5}, \\ -MDG & \text{otherwise,} \end{cases} \tag{8}$$

$$PFN = \begin{cases} 0 & \text{if } n \geqslant 1 \times 10^{6}, \\ -1 \times 10^{5} & \text{otherwise,} \end{cases} \tag{9}$$

where abs(t) is the function to get the absolute value of t.

Thus the general objective of the robust design (*GOBJ*) can be expressed as

$$GOBJ = \max\{NVMDG + PFMDG + PFN\}, \tag{10}$$

where max$\{t\}$ is the function to get the maximum of t. Then, the robust solution of the monolimb is gained when the maximum of the *GOBJ* is achieved.

3. Results

The S–N curve of the thermoplastic material [19] is shown in Fig. 6, in which the coefficients m and K of Wirsching model are 8.59 and 1.23×10^{18}, respectively. Figure 6 shows that Wirsching model has a good agreement with the test data.

The response surface models for maximum principal stress of shank at 16.9% and 45.1% of the gait cycle and dorsiflexion angle at 45.1% of the gait cycle are summed in Table 3. The functions in Table 3 are the reduced models with some trivial effects ignored.

The robust solution of monolimb of the amputee subject is: thickness of the thermoplastic material (x_1) = 4 mm, antero-posterior dimension of the shank (x_2) = 25 mm, and medial-lateral dimension of the shank (x_3) = 37.6 mm.

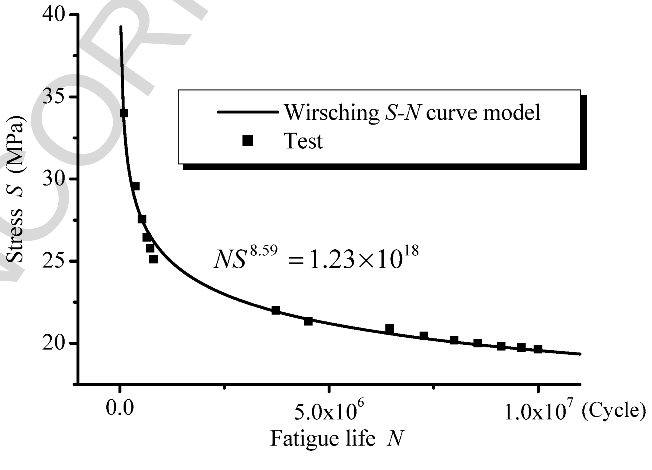

Fig. 6. The S–N curve of the polypropylene. Test data are obtained from Maier and Calafut [19].

Table 3

Response surface models of maximum principal stress at the postero-distal end of the shank at 16.9% and 45.1% of gait cycle and dorsiflexion angle at 16.9% gait cycle of monolimb

Item	Response surface model
Maximum principal stress at the postero-distal end of the shank (16.9% of gait cycle)	$100.941 - 10.99x_1 - 1.558x_2 - 1.264x_3 + 0.006x_2^2 + 0.106x_1x_2 + 0.144x_1x_3 + 0.008x_2x_3$
Maximum principal stress at the postero-distal end of the shank (45.1% of gait cycle)	$202.829 - 27.333x_1 - 3.09x_2 - 2.285x_3 + 0.811x_1^2 + 0.277x_1x_2 + 0.163x_1x_3 + 0.031x_2x_3$
Dorsiflexion angle (45.1% of gait cycle)	$50.718 - 5.674x_1 - 1.162x_2 - 0.357x_3 + 0.197x_1^2 + 0.008x_2^2 + 0.055x_1x_2 + 0.027x_1x_3 + 0.005x_2x_3$

4. Discussion

With the robust solution of monolimb of the amputee subject, the mean value of the maximum dorsiflexion angle of monolimb will be 8 degree, the variance of the maximum dorsiflexion angle of monolimb will be 1.43 degree^2, and the fatigue life of monolimb will be 1.29 million cycles. The results show that the mean value of the maximum dorsiflexion angle and the fatigue life of monolimb are brought on targets of design under the condition that the variance of the maximum dorsiflexion angle is minimized, which indicates that the use of robust design can design a monolimb with an expected fatigue life while keeping a stable prescribed dorsiflexion angle which is minimally sensitive to the variations of design variables.

The appropriate prosthetic foot dorsiflexion angle and desired fatigue life are usually the two important factors when discussing the quality of a lower-limb prosthesis. The design variables usually could not be exactly what the designers specify after the fabrication. This probably leads to unexpected prosthetic foot dorsiflexion angle and influence gait efficiency even comfort of an amputee. Therefore, it is desired to let prescribed prosthetic foot dorsiflexion angle be minimally sensitive to the variation of design variables while maintaining an expected fatigue life.

To achieve the goal, robust design may have the potential application in improving the quality of the prescribed prosthesis. With this method using finite element analysis, response surface methodology and genetic algorithm, it is possible that a prosthetist prescribes a lower-limb prosthesis with a stable prosthetic foot dorsiflexion angle and a desired fatigue life to the amputee patient.

5. Conclusion

The results of this study indicate that robust design can improve quality of monolimb by providing specified performance targets that are minimally sensitive to the variations of design variables. It is also suggested that robust design may have the potential application in improving the quality of the prescribed prosthesis.

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