

AN APPROACH FOR QUANTITATIVE EVALUATION OF TRANSFEMORAL PROSTHESIS SOCKET BY FINITE ELEMENT ANALYSIS

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ABSTRACT

Objective: The correct shaping of the socket for appropriate load distribution is a critical process in the design of lower limb prosthesis sockets. Several studies have been conducted to disclose these parameters; they can be divided into two methods: Experiment method and computation method. The finite element (FE) analysis has highly effective for study the interface pressure between the residual limb and socket. However, there is a little study focus on creating separate models of the socket and residual limb. Almost research using the same shape of socket and residual limb or using the unreal model of the socket. This study will be given some solutions for the above issues.

Methods: The author creates two models of the residual limb: Same and different with the shape of the socket. After that, the FE models were generated with appropriate conditions of the donning process. The experimental procedure was conducted for comparison and discussion with the results of the simulation.

Results: The results in case of different shape of socket and residual limb suggest that it is the better model for evaluating the interface pressure.

Conclusions: The procedure developed through this work can be used by future researchers and prosthesis designers in understanding how to better design the socket and transfemoral prostheses.

Keywords: Finite element analysis, Prosthesis, Transfemoral socket.

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INTRODUCTION

An amputated limb is one of the most physically and psychologically devastating events that can happen to a person. Not only does lower limb amputation cause major disfigurement but it also renders people less mobile and at risk of loss of independence [1]. An amputation that occurs through the femur is known as transfemoral prosthesis amputation. A transfemoral prosthesis is used as an artificial limb to restore the amputee's mobility functions for their daily life activities. It aims to effectively integrate the prosthesis as a functional extension of the body. The uppermost part of the prosthesis is called the prosthesis socket, which surrounds the residual limb and acts as a medium to transfer the load from the residual limb to the prosthesis [2]. This goal is limited by the compliance of soft tissue of the residual limb and its local tolerance to externally applied forces. In fact, the soft tissue around a residual limb is not well suited to load bearing, and an improper load distribution may cause pain and skin damage. Therefore, the correct shaping of the socket for appropriate load distribution is a critical process in the design of lower limb prosthesis sockets.

The pressure distribution on the surface of the residual limb and stress generated inside the residual limb was considered as the critical parameters for evaluating the quality of the prosthesis socket. Several studies have been conducted to disclose these parameters. There are two main methods were used, which are the experiment method [3,4] and computation method [5-9]. The experimental method involves time and costs in setting up the device. Data can be acquired only after the patient wears the prosthesis. At present, the computation method with the aid of computer was used to study for reduced time and cost to design, effective for quantifying evaluate the comfort of the socket shape with the patient's residual limb. The finite element (FE) analysis has been developed in some studies. First, the

three dimensions (3D) model of the residual limb and socket were generated by employing the computed tomography (CT) or magnetic resonance imaging (MRI) [5,10]. After that, the 3D model was meshing with appropriate element type and size. The boundary conditions were assumed for describing the operation of the lower limb with prosthesis. In most studies, the model of the residual limb and socket was assumed with the same shape or the model of the socket is not getting the reality socket shape. Zachariah and Sanders [10] used the FE analysis to compare an automated contact interface model with a gap element model, from that the interface stress in the trans-tibial prosthesis was estimated. The model of socket and residual limb in these researchs were assumed are the same. This is a simple model to reduce the time and complexity of simulation because it is focused on investigating of the difference between two types of contact between the socket and residual limb. Zhang *et al.* [11] created quite full the model of the residual limb of the transfemoral patient from the distal end to above of the hip joint. The residual model includes soft tissue and bone; the socket model assumed the same with the residual model. The simulation was taken in two steps described two states of patients using the socket: Donning and walking. The results shown there is a little deformation of residual limb, the stress almost distributed on the bottom of the socket. Winson and Lee [12] used the model of sockets which created for software and observed the von Mises stress distributions in mono-limbs with different shank designs at different walking phases. Goh *et al.* [13] developed the FE model directly from CAD data. The model was validated by comparing the FE predicted results with experimentally measured stresses for one amputee subject. However, the model of the socket was rectified from the residual limb by software. Recently, the model of socket and residual limb was obtained separately. Lacroix and Patiño [5] established the model of socket using laser scanners.

The residual was created using CT scan information. The model of the residual limb includes bone and soft tissue.

In this study, the authors using the FE analysis to evaluate the pressure on the surface of the residual limb in two cases: The shape of the socket the same and different from the residual limb. The results of the FE analysis were compared with the results of the experiment. The corresponding of pressure on the surface of the residual limb in case of different shape of socket and residual limb suggests that it is more comfortable and accurate than in case of the same shape. The correlation coefficient between results of experiment and simulation in case of different about 0.978 and in case of same shape about 0.053. The more advanced of this study was expressed in three points. First, the model of residual limb includes four parts: Skin, fat, muscle, and bone. The material of soft tissue was assumed nonlinear and different among skin, fat, and muscle. It is expected that the behavior of residual limb was the same in realistically. Second, the real model of the socket was obtained. The socket which was developed by professor Agarie [14] was used in this study. Third, the experiment was conducted parallel with the simulation. The conditions of experiments were used to set the boundary condition for simulation. In conclusion, the new approach for quantitative evaluation transfemoral prosthesis was proposed. It is hoped that this approach will allow prosthetic designers to evaluate a patient's transfemoral prosthesis fit analytically and make scientifically sound decisions on how to enhance the quality prosthesis.

METHODS

The subject in this study was a male (age 47) with a right-side transfemoral amputation. He had a height of 167 cm and weighed 61 kg without his prosthesis. The prosthesis incorporated a manual compression casting technique socket [14], a Nabco prosthesis, and an Ottobock foot.

Geometry modeling

MRI was used to obtain data of the residual limb with socket prosthesis. In the first case, the shape of the socket and residual limb is the same. The patient wore the socket prosthesis during MRI. In the case of the shape of the socket and residual limb is different, the geometry of the socket and residual limb was created separately. The residual limb was captured by MRI without socket prosthesis. The residual limb was captured as 17 layers with 10 mm separation perpendicular to the sagittal plane. Subsequently, the 3D surfaces of bone, muscle, fat, and skin were obtained. The MRI data were loaded into parallel planes, and contours manually drawn per slice and lofted into the 3D body by means of solid modeling software (PTC Creo Parametric) (Fig. 1). The model of the socket was offset from the shape of skin in the case of the shape of the socket, and residual limb is the same.

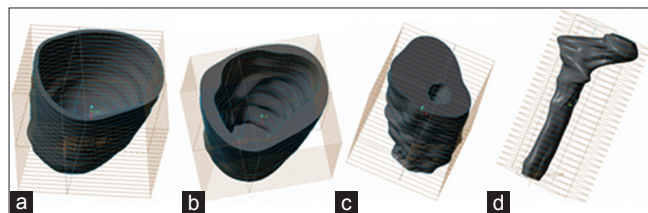


Fig. 1: Three-dimensional model of parts of the residual limb (a) skin, (b) fat, (c) muscle, (d) bone

The 3D solid models of the residual limb and socket were imported to LS-pre post for meshing and creating the properties of the simulation. Then, the simulation was run by LS-DYNA.

FE analysis procedure

Element type

The 3D model of all models was meshing with Hypermesh software (Altair Engineering). The socket was meshing as a shell element with thickness about 3 mm. The bone and soft tissue include skin, fat, and muscle were meshed with the solid element size of element about 6 mm. Tetrahedral meshes were generated on the four parts (skin, fat, muscle, and bone). These types of meshes are generally preferred over hexahedral meshes for free-form complex geometries as the former is computationally more cost effective [15] and easier to apply.

Material models

The mechanical properties of bone and socket were assumed linearly elastic, that obey Hooke's law in which stress varies linearly with strain. The materials of the parts were modeled as isotropic, with all uniform elastic properties in all directions and assumed to be homogenous with consistent material properties. The femur bone was modeled with Young's modulus of 17,700 MPa and a Poisson's ratio of 0.3 [16]. The prosthesis socket which is made from acrylic plastic was modeled with Young's modulus of 1886 MPa and a Poisson's ratio of 0.39 [17]. The soft tissue is considered as a composite material which consists of collagen fibers embedded in a softer isotropic material called ground. The strain energy function of the soft tissue material formulated by Weiss [18]. The material properties of skin, fat, and muscle were referenced from studies of Untaroiu *et al.* [19,20]. The material type 91 in LS-DYNA was used and the parameters are shown in Table 1.

Contact definitions

The first contact definition between the residual limb and the socket was a surface-to-surface contact. A coefficient of friction of 0.5 was assigned as an interaction property for the contact surfaces, as justified in Lee's *et al.* study [12]. The second contact definition applied a tied contact between bone and muscle. It provides a simple way to bond surfaces together permanently, which prevents slave nodes from separating or sliding relative to the master surface. This contact was suggested from the study of Lacroix *et al.* [5]. Based on the hypothesis about the connection between skin and fat, fat and muscle, which there is no movement relation.

Loads and boundary condition

The socket was fixed four degrees of freedom: Translation in Z-axis; rotation around X-axis, Y-axis, and Z-axis. The residual limb was moved along the Z-axis and input to the socket. The residual limb changing and fitting with the shape of the socket. The reaction force on the interface between socket and residual limb increasing depending on the movement of residual limb into the socket. At the time, the reaction force equivalent to the patient's body weight, the simulation kept stable, the interface pressure was observed and evaluated.

Fig. 2 shows the FE model of the residual limb which the same shape with socket (Fig. 2a) and different shape with socket (Fig. 2b). The FE model of socket is shown in Fig. 2c.

The LS-DYNA solver installed on HP Z440 computer was used to running process of analysis. It takes about 6 h to complete the simulation.

Table 1: Material properties of soft tissue

Name	Density (Ton/mm ³)	C ₁ (kPa)	C ₂ (kPa)	S ₁	S ₂	T ₁ (ms)	T ₂ (ms)	Bulk modulus (Mpa)
Skin	9.06E-10	0.186	0.178	0.968	0.864	10.43	84.1	20
Fat	9.06E-10	0.19	0.18	1.0	0.9	10	84	20
Muscle	1.05E-9	0.12	0.25	1.2	0.8	23	63	20

Experimental protocol

Eight triaxial force sensors NITTA PD 3-32-05-015 [21] were used in the experiment. The eight sensors correspond with eight areas of the socket were measured in two levers: Proximal level and distal end level. Four sensors were defined on four directions are anterior, posterior, medial, and lateral. The position of sensors is shown in Fig. 3.

RESULTS AND DISCUSSION

The results of the interface pressure of the experiment and simulation in the case of the shape of the socket and residual limb are the same, as shown in Fig. 4. The results of the experiment are ranging from 26.504 kPa at PD location to 53.508 kPa at AD location. However, the interface pressure of simulation in the case of the shape of the socket and residual limb is the same nearly the same with all locations, the

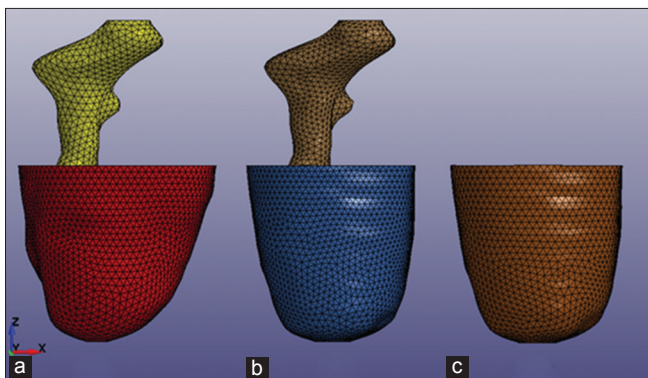


Fig. 2: The finite element model of the residual limb in case of different shape with socket (a); same shape with socket (b); and the socket (c)

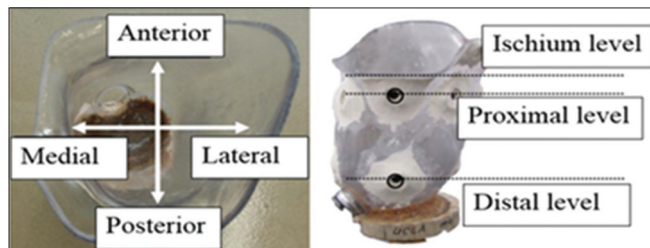


Fig. 3. The position of sensors in the socket (AP: Anterior proximal, AD: Anterior distal, MP: Medial proximal, MD: Medial distal, PP: Posterior proximal, PD: Posterior distal, LP: Lateral proximal, LD: Lateral distal)

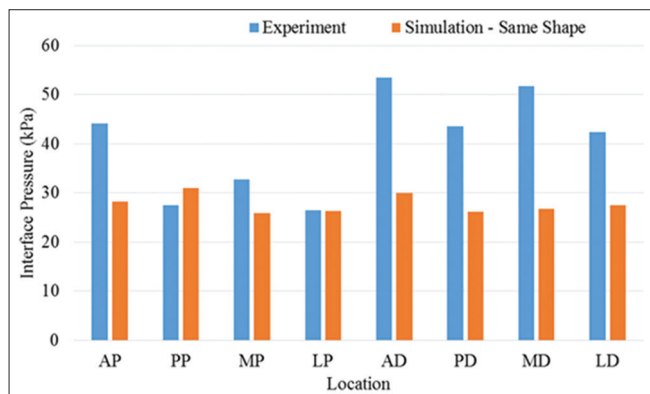


Fig. 4: Comparison of interface pressure between experiment and simulation in the case of the shape of the socket and residual limb is the same (r=0.053)

minimum value about 25.850 kPa at MP location and maximum value about 30.980 kPa at PP location. The value of interface pressure at corresponding locations does not correlate the correlation coefficient between the results of experiment and simulation about 0.053.

The comparison of interface pressure between experiment and simulation in the case of the shape of the socket and residual limb is different, as shown in Fig. 5. The value of stress distribution from 19.920 kPa at LP location to 34.290 kPa at AD location. The value of the experiment is always larger than value of simulation from 33.10% at LP location to 73.40% at MD location. However, the results of experiment and simulation have a strong correlation; the correlation coefficient about 0.978. Fig. 6 shows the relationship between experimental results and two cases of simulation results.

The results of the experiment are shown that the interface pressure generated on the surface between socket and residual limb is different, which depend on the location on the residual limb. The cause of it can come for two reasons. First, the changing of residual limb shape is not the same when wore the socket. In some areas, the shape of the residual limb is compressed, in other areas, it is extruded to fit with the shape of the socket. Second, the residual limb includes skin tissue, fat - adipose tissue, muscle tissue, and bone. The thickness of tissue layers in the residual limb is various and complex. It leads to the behavior of residual limb soft tissue is not homogeneous in all volumes.

In case of the shape of the socket and residual limb are the same, the simulation showed the value of interface pressure, which is the result of the same distortion of the residual limb in all surfaces. The behavior of the residual limb is not strong effect on the value of interface pressure. The interface pressure is not describing the actual change of the shape of the residual limb when wore the socket.

In the case of the shape of the socket and residual limb is different, the results of simulation and experiment have strong correlate. Although

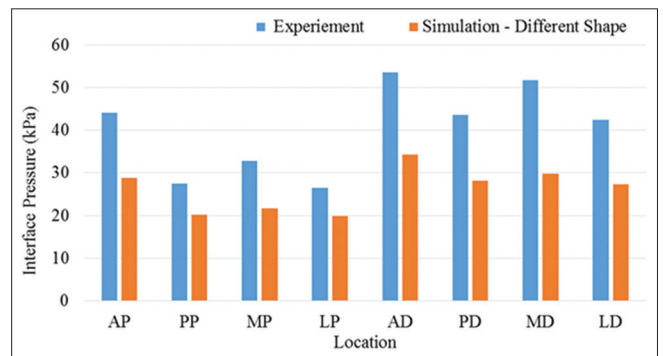


Fig. 5: Comparison of interface pressure between experiment and simulation in the case of the shape of the socket and residual limb is different (r=0.978)

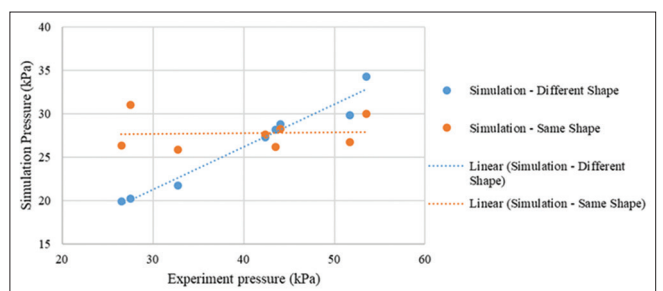


Fig. 6: The scatter diagram shows the relation between experimental results and two cases of simulation results

the value of experiment larger than the value of simulation, which expresses pretty accuracy the behavior of the residual limb in each area.

CONCLUSIONS

In this study, the FE model of the residual limb and socket was established. The residual limb includes four parts are skin, fat, muscle, and bone. Two cases with two shapes of the residual limb were built and simulated in donning socket process. The experiment with sensors for measure interface pressure between the socket and residual limb was conducted. The interface pressure of experiment, simulation in two cases was compared and evaluated. The results of this analysis, along with previous research studies, indicate that FE modeling of prosthetics must be tailored to the specific individual for whom a prosthetic device is being developed.

The results of this study suggested that using the different shape better than using the same shape of socket and residual limb for evaluating the interface pressure. Through this work, a new approach has been developed that can be used by others in modeling and analyzing the transfemoral prosthetic fit. The process starts with scanning of the amputee leg and socket, followed by developing separate CAD models for the parts of the residual limb, bone, and prosthetic socket. The CAD models, then import into FE software and assembled properly. Preprocessing operations are completed by meshing the volumes with appropriate element size and element type, assigning correct material properties, and applying contact definitions where appropriate. The results of allowing health-care providers and engineers to simulate the fit and comfort of transfemoral prosthetics to reduce the number of refits needed for amputees.

In developing more advanced FE models of the transfemoral prosthetic-limb interface, the experiment needs to conduct for confirming the material properties of the residual limb. The experimental studies on frictional coefficients can provide insight into how to better model the contact analytically. Because of the complexity of the shape of residual limb parts, the accuracy of their 3D CAD model needs to be improved.

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