Study of a flexible ankle prosthetic through the stump skin temperature

L Herdiman[1], S Susmartini[1], I Priadythama[1]

[1] Department of Industrial Engineering, Universitas Sebelas Maret, Jalan Ir. Sutami 36A, Surakarta, Indonesia

E-mail: lobesh@gmail.com

Abstract. The purpose of this study was to determine the effect on the ankle flexible prosthetic foot to the convenience of walking based on the parameters of temperature change on the surface of the skin stump on a transtibial amputee. This study using a crossover design, in which the amputee wears below knee prosthetic foot two different periods. The results of the skin surface temperature measurement when the amputee stump before running between the exoskeletal prosthetic foot without ankle and endoskeletal with flexible ankle show that p less than 0.05, which means there is no significant difference prior to the tests. Measurement of skin temperature when stump amputation after walking shows that p is more than 0.05, which means there is no significant difference after testing. Furthermore, the test walking on amputees before and after walking shows p less than 0.05, which means there are significant differences significantly to the decline in temperature on the surface of the skin stump. Concluded the use of flexible ankle on endoskeletal prosthetic foot lowers the temperature of the skin surface after walking as far as 80 meters at 0.97 percent. The decrease in skin temperature stump showed comfort in wear below knee prosthetic foot.

1. Introduction

The inspection of the health monitoring of skin on the residual limb is very important for the amputee to create an atmosphere within a comfortable walking activity. The skin is a natural barrier that lies outside to protect the tissues and organs of the body, which is composed primarily of cells and the extracellular matrix [1]. In another study, 60 to 70 percent of people with amputations were reported skin surface stump foot is stiflingly hot as a major problem [2]. The increased surface temperature of the skin on the residual limb is considered one of the main factors that can affect the health of soft tissues, especially in the area of foot stump [3, 4]. For many amputees, the high temperature in the socket caused an increase in skin problems and decreased quality of life.

Temperatures in-socket warm and moist promotes bacterial growth and skin damage, which exacerbate the sense of discomfort [5]. As described in the research by Huff *et al.* [6] and Peery *et al.* [7], the effect of temperature on the in-socket toward transtibial prosthesis users, why skin problems develop in the residual limb, how to provide system design requirements for a prosthetic foot to ease the discomfort.

An important component of the performance prosthetic for the amputee through the installation of a prosthetic foot on the stump using a socket, which is the only way to use to transfer the bodyweight between the prosthetic foot and stump in practice today [8]. Assembling to prosthetic foot between the residual limb and a prosthetic device called a part of the interface. Amputee walked activities, where the interface on prosthetic foot, that are related to the onset of friction on the skin surface of the stump with a socket. When the friction is not be overcome cause discomfort when walking and devastating effect [9, 10]. As well known, the amputee using a prosthetic foot to maintain and restore mobility capabilities upright appearance. Due to friction at the interface between the leg stump and in socket will cause the skin temperature to increase [11]. Where is allowed to continue the lasted cause of pain in the epidermal tissue and muscle tissue residual limb. Unfortunately, skin and soft tissue of the residual limb is not suitable to support the weight of the body, so the appearance of skin trauma such as skin irritation, sensitization, bruises, edema, blister and dermatitis [12]. In recent years, most researchers pay more attention to the pressure at the interface between the surface of the skin and prosthetic socket with experimental measurements and finite element analysis [13-15]. While research on the effect of the ankle on the below-knees prosthetic foot the friction at the interface no one has studied. The information obtained is not only the assessment and improvement of the design and fitting socket prosthetic but also contributed to the improvement prosthetic foot comprehensively understanding stump interface and in socket [16, 17].

The socket is a major component of the prosthetic foot that provides structural coupling, control, and transfer force at the interface with the residual limb [18]. The thermal environment in prosthetic socket causes the temperature increases, in addition to decreasing the comfort and quality of life, can put people with amputations at high risk for skin irritation. Sherwood [1], explains the skin surface temperature zone average comfortable is 33°C to 34°C. When the skin temperature reaches the limit of 35°C to 39°C, a person will feel the heat. At a temperature of 39°C to 41°C, a person will feel pain. Skin temperature is greater than 41°C, began to feel blisters. Skin temperature occurs in the shank and foot around 26.5°C to 38.3°C [3]. Comfort in the amputee to walk depends on the socket directly affect the functioning and use of prosthetic foot level [19]. Prosthetic foot effective and feasible requires good suspension to face the force that appears in the total contact socket properly when stumps foot inserted [20].

Force occurred stump foot received from the below is the ground reaction force and the above is a force of the body amputee [21]. The amount of force occurred on the prosthetic foot, due to the interaction of the stump socket during stance phase into consideration. Heel strike and toe off is determined by the detection of ground reaction force [22]. Both of these events provide a significant force against the gait is used to identify the stance phase of each step.

In the case of amputees transtibial, where the amputee has suffered the loss of shank partly, ankles and foot while retaining the remaining length of the shank and more or less of the type characteristic of weight bearing on the ankle do the normal heel phase. The flexible ankle to accommodate is the loss of the tarsus and the calcaneus, to give adequate support for the body during standing and during the stance phase of walking.

When one first stepped foot into consideration after a gait initiation of force that occurred in a socket, where the prosthetic foot leading into the stance leg, the leading leg must be placed such that the smallest possible friction interface is achieved when the inbound leg loading phase. To help is create a prosthetic foot to be more convenient and less harmless [8].

Innovation in the prosthetic foot below-knee including the flexible ankle has the ability to multi-axis with the energy store and return allows adaptation to changes in gait and reduce friction, flexible ankle fitted between SACH (Solid Ankle Cushion Heel) foot and shank made of pylons can absorb the force occur ground reaction force, where the force is absorbed saved and restored as energy during the gait cycle. All of this is that the result is accepted by the wearer under both static and dynamic conditions [23].

Measurement of the temperature of the residual limb skin interface on the skin and prosthetic foot is a necessary first step. The purpose of this study was to determine the effect on the ankle flexible prosthetic foot to the convenience of walking based on the parameters of temperature change on the surface of the skin stump on a transtibial amputee. Information skin problems caused by stump temperature increase due to friction at the interface in-socket can help in the understanding of the residual limb and can provide system design requirements for new the prosthetic foot below-knee is intended to increase the comfort of the amputee.

2. Methodology

2.1. Materials and methods
The approvals for health research ethics committee is given by the Institutional Review Board of the Universitas Sebelas Maret Surakarta (protocol number: 638/XI/HREC/2014). The approval for the study was obtained from each subject; adaptation and clarification related to testing, the use of the prosthetic foot, technical and procedures for testing and issue that requires attention be given to them before the test is carried out.

2.2. Materials
All the prosthetic foot below-knee structure is made of polyester resin in this study are the same, so there is no significant advantage in one of a subject. The weight of the two types of prosthetic feet used by amputee was almost the same, the weight of the exoskeletal prosthetic foot (1.86 ± 0.27) kg and endoskeletal (1.65 ± 0.13) kg. Height prosthetic foot anthropometry varies due to the relationship between height and length of the stump. The design of the stump socket length varies from one the subject of to another subject. Part of the shank and the socket are using a design bearing patellar tendon supracondylar (PTBSC). Part of insulation as a coating between socket and stump made of eva sheet. Stump sock made of cotton that is lithe and resilient.

2.3. Subjects
The subject is a transtibial amputee 14 (9 amputees right leg, left leg amputee 3) with age (27.50 ± 7.37) years, body weight (66.02 ± 7.78) kg, height (163.71 ± 7.63) cm, body mass index (20.19 ± 1.62) kg/m2, the anthropometry of the length of the knee to foot a sitting position (45.11 ± 2.71) cm, and the experience of wearing a prosthetic foot (8.14 ± 6.48) years.

2.4. Procedures of study
The subject was permitted to use the prosthetic limb he normally used, to gain a natural walking posture. Thus, it has provided accurate data that represents actual gait. Subject to walked as far as 80 meters with a distance of 10 meters by shuttle [24].

The time it takes for the test runs about 6 minutes with a walking speed of about 1.20 to 0.15 m/s [25, 26]. Measurement of the temperature of the surface of the skin stump performed on six points at the posterior (P) and anterior (A) in accordance with the pressure on the stump [21, 27], consists of a proximal medial, proximal lateral, proximal anterior, distal medial, distal lateral and distal anterior, can be seen in Figure 1.

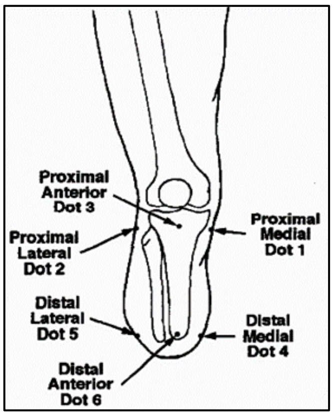

Figure 1. Measurement dots on skin stump surface.

Skin stump surface temperature gauges using a non-contact digital thermometer with LCD HDT8808. Skin surface measurement stump on the subject was divided into before and after walking. The amputee of the convenience of walking included characterized by a lack of stump skin temperature, although not significant. Subjects were allowed to rest for 3 minutes as needed, between walks test.

2.5. Study design
The method in this empirical study was a crossover design in Period I and Period II [28]. The number of subjects in these studies 14 subjects, who were divided into each group of 7 subjects. The period I, group I wear to exoskeletal prosthetic foot without ankle and group II wear to endoskeletal prosthetic foot with a flexible ankle. Period II, a group I continued to endoskeletal prosthetic foot with a flexible ankle and group II continued to exoskeletal prosthetic foot without ankle. Time of washing out was given two days prior to the second treatment period, adjusted to the time of adaptation on the subject, eliminating the effect of treatment during Period I.

2.6. Statistical analysis
In this study, all data were presented as $\mu \pm \sigma$. IBM SPSS version 20.0 statistics was utilized for data analysis. The statistical differences of skin temperature stump among different groups were determined by analysis with independent t-test and pair t-test. The level of statistically significant was set to $p < 0.05$. All the statistical differences resulted from the comparison between group amputee wearing exoskeletal foot prosthesis without the ankle and endoskeletal foot prosthesis with a flexible ankle, and between the two periods.

3. Results and discussion

3.1. The prosthetic foot below-knee
Figure 2 shows exoskeletal prosthetic foot is in the design without the ankle is made of polyester resin with the outer skin of laminated plastic and urethane foam interior added. The strength provided by the outer laminate and cosmetic is an integral part of the prosthetic foot.

Figure 2. The prosthetic foot below-knee (exoskeletal prosthetic foot without ankle and endoskeletal prosthetic foot with a flexible ankle).

The endoskeletal prosthetic foot is built from several modular components. Prosthetic as a whole is custom made from a socket, the calf, the torque absorber, a unit of the ankle, and foot. The structural strength of the component is formed as the central skeleton. External design and removable, soft foam material are coated with a rod pylon, skin stimulation as a wrapper. This study was designed for flexible ankle with two main functions: multi-axis and energy store and return. The multi-axis ankle joint intended, in which ankle has the ability to perform the movements consisting of dorsiflexion, plantar flexion, eversion, inversion. As for the energy storage and return is designed to accommodate the ankle joint during the walking motion of the stance phase to the swing phase.

Flexible ankle with energy store and return in the stance phase of gait as a human elastic element is tightened while the motion forward, the prosthetic ankle approximately stores energy up to +8°. Amputee feels comfortable with the weight of the mass to exoskeletal prosthetic foot about 1.86 kg and endoskeletal prosthetic foot about 1.65 kg, despite the fact that the weight of this approach is a replacement for body parts missing limb. The prosthetic foot below-knee that the belief with all the components are combined into a single unit, which is expected this design can transfer loads principle [29].

3.2. Statistical analysis

The result of Shapiro-Wilk test and the Levene's test for the temperature of the skin stump showed that all the data in two groups in Period I and Period II is normal distributed and homogeneous (with p-value > 0.05). Tests conducted with a crossover design, tests of comparability required for the temperature of the skin stump, the results showed there was no significant difference (with p-value > 0.05).

In addition, the temperature of the skin stump are equal and treated equally between Period I and Period II, which was originally between Group I wearing exoskeletal prosthetic foot without ankle which is continued to wearing endoskeletal prosthetic foot with a flexible ankle and Group II wearing endoskeletal prosthetic foot with a flexible ankle which is continued to wearing a prosthetic foot exoskeletal without ankle.

The results of the period test and carry-over effect test to the temperature of the skin stump was showed that no significant difference ($p > 0.05$). This shows that the Group I (exoskeletal prosthetic foot without ankle followed by endoskeletal prosthetic foot with a flexible ankle), and Group II (endoskeletal prosthetic foot with a flexible ankle followed by exoskeletal prosthetic foot without ankle) is the same, which means the entire participant, are equal and treated equally. The decrease in the surface of the skin stump is due to the difference in treatment interventions.

The independent sample t-test compares one means of a distinct group to the mean of another group from the same sample. Measurements before testing (pre) was conducted for the temperature of the skin stump wearing between exoskeletal prosthetic ankle and foot without endoskeletal prosthetic foot with a flexible ankle, which is showed that $p < 0.05$, the means for the temperature of the skin stump no significant difference prior to the tests, where the temperature of the skin stumps are equal and treated equally, shown in Table 1.

Table 1. The result of independent t-test for the temperature of the skin stump the pre-test (before walk) – mean (±SD).

The Prosthetic Foot Below-Knee	The Temperature of The Skin Stump (°C)		
	Mean (SD)	Diff. Means	Value-p
Exoskeletal without ankle	33.61 (0.51)	0.70	0.001
Endoskeletal with flexible ankle	33.91 (0.52)		0.001

Measurement after the test (post) was conducted to the temperature of the skin stump wearing between exoskeletal prosthetic without ankle and endoskeletal prosthetic foot with a flexible ankle, which is showed that $p > 0.05$, the means for the temperature of the skin stump was significantly different after testing, where the temperature of the skin stumps are equal and treated equally, in which the temperature of the skin stumps are equal and treated equally, shown in Table 2.

Table 2. The result of independent t-test for the temperature of the skin stump the post-test (after walk) – mean (±SD).

The Prosthetic Foot Below-Knee	The Temperature of The Skin Stump (°C)		
	Mean (SD)	Diff. Means	Value-p
Exoskeletal without ankle	33.94 (0.12)	0.33	0.085
Endoskeletal with flexible ankle	33.61 (0.13)		0.085

A paired t-test of the comparative test between treatments within each group for the temperature of the skin stump was determined to differentiate between exoskeletal prosthetic foot without ankle and endoskeletal prosthetic foot with a flexible ankle. The results showed that a significant difference ($p < 0.05$); it means the intervention can decrease for the temperature of the skin stump after the amputee walking. Interventions with a flexible ankle prosthetic foot to make the interface between the surface of the skin in socket stump with not much friction that makes the skin surface temperature increases, shown in Table 3.

Table 3. The result of pair t-test for the temperature of the skin stump – Mean (±SD).

The Prosthetic Foot Below-Knee	The Temperature of The Skin Stump (°C)			
	Mean (SD)	Diff. Means	Value-t	Value-p
Exoskeletal without ankle	33.94 (0.47)	0.33	2.346	0.035
Endoskeletal with flexible ankle	33.61 (0.49)			

The means of the temperature of the skin stump to pair t-test showed significant differences ($p < 0.05$). Usage of the exoskeletal prosthetic foot without ankle and endoskeletal prosthetic foot with a flexible ankle give an average of (33.94 ± 0.47)°C and (33.61 ± 0.49)°C, respectively. Huff *et al.* has reported after wearing a prosthetic foot, the average temperature of the residual limb down about 0.4°C to achieve rest, in which the initial steady state temperature (29.5 ± 0.9)°C during the last minute of the start of a period of rest during the 1 hour [6]. After the training period begins, the average residual limb increased sharply even after 30 minutes of walking on a treadmill with self-selected speeds. The temperature of the residual limb during the last minute of a 30-minute walk on a treadmill is (32.6 ± 0.8)°C. After reaching the top overall resume walking 32.8°C, the temperature began to decline during the late break. The temperature of the residual limb during the last minute of the end of the rest period was (32.6 ± 0.6)°C, or 3.1°C higher than the average temperature before exercise. The minimum temperature for the last minute rest is 28.1°C and the maximum was 31.3°C. Running on the treadmill was showed that skin temperature increased quite uniformly on the lower extremity with a minimum of 31.1°C and maximum 34.1°C during the last minutes of walking.

Mathur *et al.* have reported of donning because moderate temperature increases, walk led to a significant increase, and time off following activities should be substantially longer for the return of the body to temperature before wearing prosthetic foot [4]. Profile residual limb temperature to the ambient temperature of 10°C and 15°C has the same pattern to be stable throughout the experiment. However, this residual limb temperature profile is significantly different from that at room temperature 20°C and 25°C. Both residual limb skin temperature lateral and medial showed a steady increase in the temperature of the entire trial. After the end of the experiment, the temperature in both the lateral and medial sides is 2.1°C higher than before. In case there is a layer of the prosthetic foot socket liner and materials that inhibit the body's ability to thermoregulation effectively.

Based on the above results, there is a period of adaptation in the amputee wearing a prosthetic foot. Adaptation time could depend on the friction behaviours of materials and the design of prosthetic foot to the residual limb interface with in-socket, trauma to the skin and individual differences. In this way, the condition of the friction that occurs in the prosthetic socket will be shortened and the risk of skin trauma will decrease, thereby improving the convenience of walking.

4. Conclusions

A flexible on endoskeletal prosthetic foot ankle is well functioning in reducing the force that causes friction between the surface of the skin stump and in-socket. Temperature stump skin prior to the tests showed no significant difference, which means the two groups in the same condition between exoskeletal prosthetic ankle and foot without endoskeletal prosthetic foot with a flexible ankle. For an amputee, after the activity went as far as 80 meters showed a significant difference after testing, this means that the two groups there are differences in skin surface temperature with a difference of 0.33°C. Tests walking on amputee between before and after there is a significant difference to the decrease of the temperature on the skin surface of the stump at 0.97%. The decrease in skin temperature stump is associated with increased wearing comfort to the amputee in a prosthetic foot.

5. References

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