Factors Associated with Prosthetic Looseness in Lower Limb Amputees

Thong Phonghanyudh MD*,
Taweesak Sutpasanon MD*, Chanasak Hathaiareerug MD*,
ML Buddhibongsa Devakula MD**, Wipoo Kumnerddee MD*

** Department of Rehabilitation Medicine, Phramongkutklao Hospital and College of Medicine, Bangkok, Thailand*
*** Prostheses Foundation of H.R.H. the Princess Mother, Chiang Mai, Thailand*

Objective: *To determine the factors associated with prosthetic looseness in lower limb amputees in Sisaket province.*
Material and Method: *The present was a cross-sectional descriptive study. Subjects were lower limb amputees who previously obtained prostheses and required prosthetic replacements at the mobile prosthetic laboratory unit under the Prostheses Foundation of H.R.H. the Princess Mother at Khun Han Hospital, Sisaket province, in February 2013. Data including participant characteristics, prosthetic looseness data, and various variables were collected by direct semi-structured interview. Energy expenditures in physical activities were measured using the Thai version of the short format international physical activity questionnaire. Data between participants with and without prosthetic looseness were compared to determine prosthetic loosening associated factors.*
Results: *Among 101 participants enrolled, 33 (32.7%) had prosthetic looseness with average onset of 1.76±1.67 years. Diabetes mellitus was the only significant factor associated with prosthetic looseness from both univariate and multivariate analyses (HR = 7.05, p = 0.002 and HR = 5.93, p = 0.007 respectively).*
Conclusion: *Among the lower limb amputees in Sisaket province, diabetes mellitus was the only factor associated with prosthetic looseness. Therefore, diabetic screening should be supplemented in lower limb amputee assessment protocol. In addition, we recommend that amputees with diabetes mellitus should receive prosthesis check out at approximately one year.*

Keywords: *Prosthetic looseness, Lower limb amputees, Prostheses Foundation, Sisaket province*

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The survey in 2007 found 23,777 lower limb amputees among the 65,566,359 people in Thailand[1], which is equal to the rate of 36.26 per 100,000 people. Most causes of the amputations include injuries, diabetes mellitus, vascular disease, and malignancy[2,3]. Lower limb amputation impacts multiple aspects of an individual's life, i.e., body image, self-care activities, mobility, psychosocial health, vocational, and avocational opportunities[4]. Rehabilitation and prosthetic interventions offer tremendous potential for improvement of amputee physical functioning, emotional well-being, and quality of life[5].

Previous study revealed that the overall lifespans of the lower limb prostheses ranged from one month to 12 years, with an average of three years[6]. Mostly the sockets of prostheses are readjusted for several times during the first 18 months after amputation due to the stump shrinkage[7]. After a period of time, 30 to 100% of the amputees report complications or problems from the prostheses[8,9]. One of those problems is the prosthetic looseness condition, which manifested as stump pain, reduction in rotational control, increased tendency to piston, and skin breakdown[10].

In the mature stump, the prosthetic looseness is related to a decrease in volume of the stump, which can be attributed to muscle atrophy or weight loss[10]. However, other factors associated with the prosthetic looseness have not yet been extensively studied. The authors hypothesized that there may be some modifiable factors contributing to prosthetic looseness. The knowledge might be applied to extend the prosthetic life spans then reduce the cost of prosthetic replacement in the future.

In the present study, the authors collected the data of previous prostheses from the lower limb amputees, in order to determine the significant factors associated with prosthetic looseness condition.

Correspondence to:
Phonghanyudh T, Department of Rehabilitation Medicine, Phramongkutklao Hospital and College of Medicine, Ratchathewi, Bangkok 10400, Thailand.
Phone: +66-2-3547711
E-mail: thongcud34@hotmail.com

Material and Method

The present study was approved by the Institutional Review Board, Royal Thai Army Medical Department, and was conducted in the mobile prosthetic laboratory unit under the Prostheses Foundation of H.R.H. the Princess Mother. Many times a year, the mobile laboratory unit consisting of team of physiatrists and prosthetists travels to remote areas to provide free prostheses for amputees particularly those with limited socioeconomic status. For the present study, mobile prosthetic laboratory at Khun Han Hospital, Sisaket province was chosen as venue of investigation.

All lower limb amputees receiving mobile prosthetic laboratory service were asked to participate in the present study. Individuals who were willing to participate were carefully checked as followings. All participants must be lower limb amputees who previously obtained prostheses and required prosthetic replacements. The exclusion criteria were: 1) age below 20 years old, 2) previous prostheses received within the first 18 months after amputation, 3) inability to answer the questions, such as those with impaired speech, hearing, mental, or schizophrenia, and 4) patient refusal. On the basis of finite population of 138 amputees, the average number of amputees receiving prosthetics on the previous year, 100 participants were needed to detect 36% incidence[11] with 5% error, and 95% confident interval (CI). Considering 30% drop out rate, 142 participants were enrolled to this recent study. Data of the latest prostheses including participant characteristics, prosthetic looseness data, and independent variables, were collected using direct semi-structured interview.

Prosthesis looseness was diagnosed by one physician who had approximately two years experience in clinical evaluation of the amputees. Criteria of looseness were established based on the characteristics of prosthetic looseness condition[10] plus opinions from experts in prosthetics. Looseness was determined if the participants perceived the loose socket plus one of the following criteria: 1) the participants perceived more difficulty for rotational control, 2) the participants perceived more piston action, or 3) five or more socks were needed to cover each stump. There were four types of lower limb prosthetics including trans-femoral prosthetics, knee disarticulation prosthetics, trans-tibial prosthetics and ankle disarticulation prosthetics. All prostheses provided consisted custom-made plastic socket with endoskeletal shank and solid ankle foot. Prosthetic knee units provided were four-bar linkage type made by the Prostheses Foundation of H.R.H. the Princess Mother project.

The independent variables included age at the time the participants received the latest prostheses, sex, cause of amputation, level of amputation, functional level, diabetes mellitus, vascular disease, weight loss condition, energy expenditure in total physical activity per week, stump strengthening exercise, looseness or discomfort since first wearing, and duration of prosthetic usage per week.

Energy expenditure in physical activity was measured using the Thai Version Short Form International Physical Activity Questionnaire (Thai short IPAQ). The questionnaire estimates energy expenditure in metabolic equivalents based on duration of physical activity in one week. Thai short IPAQ gives accuracy (rS) and the reliability (ICC) of 0.32 and 0.69, respectively[12]. Since walking with prosthesis expends more energy than walking with true legs, energy estimated from Thai short IPAQ were multiplied by 1.63, 1.25, and 1.43 for those wearing unilateral transfemoral, transtibial, and Syme's prosthesis, respectively[13,14].

Statistical analysis

The data were analyzed using STATA12 software (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP). Descriptive statistics were analyzed for the demographic data. Survival analysis was used to determine the factor associated with the prosthetic looseness. Multivariate analysis was performed to adjust age when received prosthesis, sex, and any variable which p-value from univariate analysis was less than 0.150. To compare the onset of prosthetic looseness among the independent variables, Mann-Whitney U test, Kruskal-Wallis test, and Spearman's rank correlation coefficient were performed. The p-value of less than 0.05 was considered as statistically significant.

Results

Among the 142 amputees screened, 101 met the eligible criteria. Forty-one amputees were excluded as the followings: one was younger than 20 years old; 24 amputees received the latest prostheses within the first 18 months after amputation; and 16 amputees refused to enter the study. All participants were unilateral amputees. Demographic data were shown in Table 1.

Of all participants, 33 (32.7%) amputees were determined as prosthetic looseness. Average onset of

prosthetic looseness was 1.76±1.67 years. Analysis of factors associated with prosthetic looseness was shown in Table 2. Diabetes mellitus was the only one significant factor associated with prosthetic looseness from both univariate (HR = 7.05 (2.07, 23.99), p = 0.002) and multivariate analyses (HR = 5.93 (1.62, 21.64), p = 0.007), respectively. The onset of prosthetic looseness was not associated with any independent variables, as shown in Table 3. Estimated median survive was 88 months 95% CI (33.24-142.76), as shown in Fig. 1. Median onset of prosthetic looseness was 11 (5, 11) and 14 (8.25, 29) months in diabetic and non-diabetic amputees, respectively.

Table 1. Participants' characteristics

	Mean ± SD or n (%) n = 101
Age when received prostheses (year)	47.54±15.13
Age when being amputated (year)	31.60±14.68
Body mass index (kg/m^2)	21.56±3.17
Male, n (%)	91 (90.1)
Educational level	
Never studied	8 (7.9)
Elementary school	66 (65.3)
Middle school	6 (5.9)
High school	13 (12.9)
Undergraduate	2 (2.0)
Graduate	6 (5.9)
Occupation	
Agriculturist	59 (58.4)
Technician	8 (7.9)
Private practitioner	8 (7.9)
Official	5 (5.0)
Others	7 (6.9)
Unemployed	14 (13.9)
Causes of amputation	
Injury	86 (85.1)
Congenital	6 (5.9)
Infection	4 (4.0)
Malignancy	3 (3.0)
Diabetes mellitus	1 (1.0)
Vascular disease	1 (1.0)
Levels of amputation	
Transfemoral amputation	28 (27.7)
Transtibial amputation	70 (69.3)
Syme's amputation	3 (3.0)
Oder of the latest prostheses	
The 1st prosthesis	4 (4.0)
The 2nd prosthesis	18 (17.8)
The 3rd prosthesis	10 (9.9)
The 4th or more	69 (68.3)
Functional level	
Non-ambulator	3 (3.0)
Household ambulator	6 (5.9)
Limited community ambulator	6 (5.9)
Community ambulator	83 (82.2)
Athlete	3 (3.0)

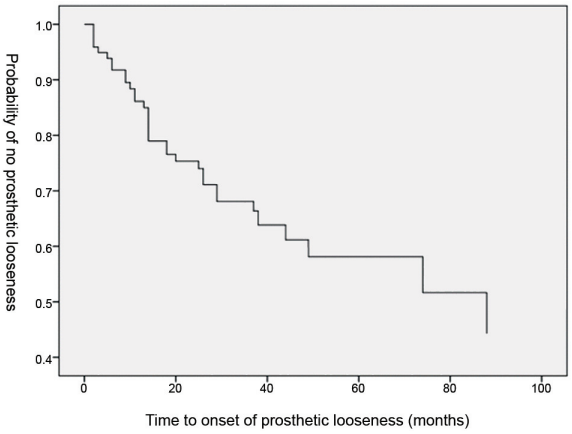

Fig. 1 Probability of no prosthetic looseness over time.

Discussion

The authors found that diabetes mellitus was the only factor associated with the prosthetic looseness, while other factors of interest did not showed significant association with prosthetic looseness. To our knowledge, this was the first study to determine the factor associated with the looseness of the prostheses. Diabetes mellitus can induce muscle atrophy by losing insulin signaling to skeletal muscle[15]. Consequently, stump volume might decrease more rapidly in diabetic than non-diabetic amputees, thereby leading to relative socket looseness. Moreover, fluctuating stump volume is a significant problem in diabetic amputees[16], and might be another reason responsible for occurrence of prosthetic looseness in the present study.

Generally, level of physical activity over 1,200 MET•min•wk^{-1} was high enough for individuals to lose weight[17] and tend to reduce corresponding residual limb volume fluctuation[18]. Moreover, there is a muscular activity pattern when walking with the prosthesis similar to that of a normal leg[19]. The muscular activity may retard muscle atrophy rate as well as stump volume reduction. As a result, the author expected that prosthetic socket of individuals with high level of physical activity might have less problem of loosening socket. However, results from the present study did not show significance of physical activity level to prosthetic looseness. It probably because all effects from physical activity occurred at too small extent to prolong stump shrinkage.

Table 2. Analysis of factors associated with prosthetic looseness

Factors	Univariate analysis		Multivariate analysis	
	HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Age when received prostheses	1.02 (1.00, 1.05)	0.047*	1.02 (0.99, 1.05)	0.081
Male sex	0.50 (0.19, 1.30)	0.153	0.69 (0.23, 2.04)	0.503
Body mass index	1.04 (0.94, 1.16)	0.427		
Causes of amputation				
Injury	1			
Others	1.12 (0.43, 2.90)	0.825		
Level of amputation				
Transfemoral amputation	1			
Transtibial and Syme's amputation	1.50 (0.65, 3.46)	0.325		
Functional level				
Non-ambulator	1			
Household ambulator	0.72 (0.10, 5.16)	0.744		
Limited community ambulatory	0.82 (0.14, 4.90)	0.825		
Community ambulatory and athlete	0.90 (0.21, 3.82)	0.889		
Diabetes mellitus	7.05 (2.07, 23.99)	0.002*	5.93 (1.62, 21.64)	0.007*
Weight loss condition	1.87 (0.84, 4.16)	0.125	1.82 (0.78, 4.25)	0.165
Energy expenditure <1,200 MET•min•wk^{-1}	3.29 (0.99, 10.88)	0.051	2.82 (0.71, 11.19)	0.141
Exercise stump correctly	1.08 (0.45, 2.64)	0.858		
Looseness since the first time received	0.80 (0.19, 3.37)	0.764		
Discomfort since the first time received	0.94 (0.39, 2.30)	0.899		
Duration of prosthetic usage per week (hours)	0.998 (0.99, 1.01)	0.592		

* Statistically significance, $p<0.05$

Surprisingly, standard stump exercise did not alleviate prosthetic looseness in the present study. The result is contrary to the concept believed generally so that stump exercise has been widely emphasized and always included in rehabilitation protocol for lower limb amputees. It is probably because the standard exercise program, in fact, could not significantly prevent shrinkage of the stump. Since there has no study investigating effects of exercise to stump volume, the authors assume that strengthening exercise may induce both decreased fat mass and increased fat-free mass[20]. The amputees who practices stump-strengthening exercise correctly may still have stump shrinkage if the fat reduced more prominently than the increase in fat-free mass. Moreover, there were a relatively high number of amputees due to explosive devices in the venue of investigation. Hence, there may be more soft tissue loss among participants in the present study than that of other population.

The results of the present study demonstrated that prosthetic looseness condition was common. Consequences from prosthetic looseness such as stump pain and wound including the need for frequent prosthetic replacement may affect daily livings of the amputees. According to our findings, diabetes mellitus with the prosthetic looseness emphasizes the importance of the stump and prosthetic care in the amputees with diabetes. Screening lower limb amputees with diabetes before prosthetic fitting process may be useful. Amputees with diabetes may require more post-amputation rehabilitation, careful prosthetic selection, and closer follow-up after receiving prostheses. According to our results, diabetic and non-diabetic amputees should be scheduled to prosthetic check-up by 11 and 14 months, respectively. In addition, diabetic amputees may have higher expense in prosthetic care compared with those without diabetes.

The present study had a cross-sectional design; therefore, no temporal relation between the significant factors and prosthetic looseness can be inferred. Secondly, data collection using semi-structured interview might be of less reliable compared with those using standardized questionnaire. However, there was only one physician who was familiar with amputation problems collected the data, inter-rater difference has already been eliminated. However, reliability of some

Table 3. Comparison of onset of prosthetic looseness among the independent variables

	n	Onset of looseness (year)	*p*-value
Sex			0.563
Male	28	1.86±1.78	
Female	5	1.20±0.56	
Cause of amputation			0.705
Injury	28	1.81±1.76	
Congenital	2	2.00±1.65	
Infection	2	1.59±0.83	
Diabetes mellitus	1	0.42	
Level of amputation			0.055
Transfemoral amputation	7	2.40±1.32	
Transtibial amputation	26	1.59±1.73	
Diabetes mellitus			0.511
Yes	3	1.05±0.67	
No	30	1.83±1.73	
Weight loss condition			0.193
Yes	8	1.03±0.69	
No	25	2.00±1.82	
Energy expenditure in total physical activity			0.347
<1,200 MET•min•wk^{-1}	3	2.11±1.09	
≥1,200 MET•min•wk^{-1}	30	1.73±1.72	
Stump strengthening exercise			0.455
Performed correctly	6	1.14±0.69	
Performed incorrectly or not performed	27	1.90±1.79	
Looseness while wearing since the first time received			0.385
Yes	2	0.92±0.12	
No	31	1.82±1.71	
Discomfort while wearing since the first time received			0.513
Yes	6	1.47±1.34	
No	27	1.83±1.75	

data may be limited since information collected by interviewing was subjective and retrospective. Thirdly, the participants represent only the lower limb amputees in Sisaket province, which may not represent general Thai population. Sisaket province is a border province used to be the war field in the past. Therefore, incidence of traumatic cases was relatively high. Injury due to explosions was susceptible to extensive tissue loss affecting volumes of the stumps. Different characteristics of study's participants may give different result. Lastly, there has never been an existing prosthetic looseness criteria prior to this study. The criteria in the present study were mostly subjective, and parts of them were established from the expert opinion. Different criteria of socket looseness may lead to different significant factors. The author recommends that effects of exercise and physical activity to stump volume should be investigated in different population in the future to confirm our findings. Aspect of rehabilitation and health economics in amputee should be segmented between diabetic and non-diabetic population.

Conclusion

Among the lower limb amputees in Sisaket province, diabetes mellitus was the only factor associated with prosthetic looseness. Therefore, diabetic screening should be included in lower limb amputee assessment protocol. In addition, we recommend that amputees with diabetes mellitus should receive prosthesis check-up at approximately one year.

What is already known on this topic?

One of the common lower limb prosthetic complication is the prosthetic looseness condition, which is usually related to residual limb volume decrease by muscle atrophy or weight loss. Diabetes

mellitus can induce muscle atrophy by losing insulin signaling to skeletal muscle and the diabetic amputees are reported to have more rapidly decrease and significant fluctuating in residual limb volume.

The level of physical activity over 1,200 MET•min•wk^{-1} is able to loose individuals weight and reduce residual limb volume fluctuation. In addition, stump exercise has been widely encouraged in rehabilitation protocol for lower limb amputees.

What this study adds?

The only factor associated with prosthetic looseness in this study is diabetes mellitus. The finding supports diabetic screening in the lower limb amputee assessment protocol, and those amputees with diabetes mellitus should receive prosthetic check-up at approximately one year. However, the lower level of physical activity was not a factor associated with prosthetic looseness, which was probably because its effects to stump volume occurred at small extent so that it was not sufficient to cause significant socket looseness. Moreover, the standard stump exercise did not alleviate prosthetic looseness which probably because it, in fact, could not significantly prevent shrinkage of the stump or the decrease in fat mass had a greater effect than the increase in fat-free mass. The effects of exercise and physical activity to stump volume should be investigated in different population in the future to confirm our findings.

Potential conflicts of interest

None.

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ปัจจัยที่มีความสัมพันธ์กับปัญหาขาเทียมหลวมของผู้ใช้ขาเทียม

ธง พงษ์หาญยุทธ, ทวีศักดิ์ สูตรภาษานนท์, ชนศักดิ์ หทัยอารีย์รักษ์, พุฒิพงศ์ เทวกุล, วิภู กำเหนิดดี

วัตถุประสงค์: *เพื่อศึกษาปัจจัยที่มีความสัมพันธ์กับการหลวมของขาเทียมในผู้ใช้ขาเทียมที่จังหวัดศรีสะเกษ*
วัสดุและวิธีการ: *การศึกษานี้เป็นการศึกษาเชิงพรรณนา ณ จุดเวลาใดเวลาหนึ่ง ศึกษากลุ่มผู้ใช้ขาเทียมที่เคยได้รับขาเทียมมาก่อนและมาขอรับบริการเพื่อเปลี่ยนขาเทียมที่หน่วยทำขาเทียมพระราชทานเคลื่อนที่ของมูลนิธิขาเทียมในสมเด็จพระศรีนครินทราบรมราชชนนี ณ โรงพยาบาลขุนหาญ จังหวัดศรีสะเกษ ในเดือนกุมภาพันธ์ พ.ศ. 2556 เก็บรวบรวมข้อมูลซึ่งประกอบด้วยลักษณะของผู้ใช้ขาเทียม ข้อมูลการหลวมของขาเทียม และตัวแปรต่าง ๆ โดยทำการสัมภาษณ์แบบกึ่งโครงสร้างโดยตรง วัดค่าพลังงานที่ใช้ในกิจกรรมทางกายโดยรวม โดยใช้แบบสอบถามสากลเรื่องกิจกรรมทางกายชุดสั้นฉบับภาษาไทย เปรียบเทียบข้อมูลระหว่างกลุ่มผู้ที่มีภาวะขาเทียมหลวมและกลุ่มผู้ที่ไม่มีภาวะขาเทียมหลวมเพื่อหาปัจจัยที่มีความสัมพันธ์กับภาวะขาเทียมหลวม*
ผลการศึกษา: *ในกลุ่มผู้ใช้ขาเทียมที่เข้าเกณฑ์การศึกษา 101 ราย พบผู้ที่มีภาวะขาเทียมหลวมจำนวน 33 ราย (ร้อยละ 32.7) ระยะเวลาเฉลี่ยในการเกิดขาเทียมหลวมเท่ากับ 1.76±1.67 ปี ปัจจัยสำคัญที่มีความสัมพันธ์กับการหลวมของขาเทียมมีเพียงโรคเบาหวาน ทั้งจากการวิเคราะห์สถิติเอกนาม (HR = 7.05, p = 0.002) และการวิเคราะห์สถิติพหุนาม (HR = 5.93, p = 0.007)*
สรุป: *ในกลุ่มผู้ใช้ขาเทียมที่จังหวัดศรีสะเกษ ปัจจัยสำคัญที่มีความสัมพันธ์กับการหลวมของขาเทียมมีเพียงโรคเบาหวาน ดังนั้นแนวทางการประเมินผู้ใช้ขาเทียมจึงควรเพิ่มการตรวจคัดกรองโรคเบาหวานด้วย นอกจากนี้ยังแนะนำให้ผู้ใช้ขาเทียมที่เป็นโรคเบาหวานนำขาเทียมเข้ารับการตรวจประเมินสภาพปีละหนึ่งครั้งโดยประมาณ*
