

Relationship between Service Provision and the Use of Trans-tibial Prostheses: a Study from Sirindhorn School of Prosthetics and Orthotics in Thailand

Dacharux W and Nutchamlong Y

Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital,
Mahidol University, Bangkok, Thailand

ABSTRACT

Objectives: To study servicing factors related to the use of trans-tibial prosthesis.

Study design: Retrospective study.

Setting: Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital

Subjects: Amputees who received trans-tibial prostheses and completed follow-up during May 2019 to February 2020

Methods: The data collection was done by reviewing the participants' medical records and follow-up forms. The data of the participants and of the most recent prosthesis which had been used for at least one month was retrieved. The participants were divided into daily-user and non-daily-user groups.

Results: There were 44 participants. The median age was 56 years. The most common cause of amputation was trauma (40.9%). Most of them had underlying disease (68.2%) and had problems after receiving the prosthesis (68.2%). Twenty-nine participants (65.9%) used the prosthesis every day. Comparing between the two groups, statistically significant difference was found for receiving the prosthesis from less experienced prosthetists and less time from casting to fitting day. ($p = 0.026$ and 0.006 , respectively). The only factor affecting the every-day use of prosthesis was the time from casting to fitting day (odds ratio = 5.4, 95% CI 1.3-22.7). The cut-off duration for casting to fitting day was 21 days.

Conclusion: Most of the amputees who received the trans-tibial prosthesis from Sirindhorn School of Prosthetics and Orthotics used the prosthesis every day. The only factor affecting the everyday use of prosthesis is the time from casting to fitting day. The cut-off duration for casting to fitting day was 21 days.

Keywords: leg prosthesis, artificial limb, amputees

ASEAN J Rehabil Med. 2020; 30(3): 89-96.

Introduction

In 2012 there were 1,478,662 persons with disability in Thailand. Of those, 13,562 disabled had to use prostheses. Trans-tibial prosthesis accounted for the most proportion at

61%⁽¹⁾ which was near the number from Australia at 63.6%⁽²⁾ and Vietnam at 65.5%⁽³⁾. Nowadays, there should be more demand for trans-tibial prosthesis due to the increased number of the disabled of the whole country.⁽⁴⁾ The conditions in need of trans-tibial prosthesis could be acquired trans-tibial or below-knee amputation or congenital limb deficiency. The process of providing a trans-tibial prosthesis starts from a doctor's prescription, mostly a rehabilitation doctor (physiatrist) or an orthopaedic doctor (orthopedist). Then, an amputee will be re-assessed by a prosthetist and casted for a model stump. The prosthetist will rectify and assemble every component into alignment before appointing the patient to fit the prosthesis and deliver it. A follow-up is usually done at one to four weeks' time.

There have been less prosthetics studies from developing countries and lesser about prosthetic services provision. Quantity is usually used as a measure. In 2005, Jensen JS and colleagues developed and tested a set of quality benchmarks for trans-tibial prosthesis in developing countries.⁽⁵⁾ They used the components made of polypropylene and assembly system from the International Committee of the Red Cross (ICRC). Based on their results, the International Society for Prosthetics and Orthotics (ISPO) established user-relevant measures as percentage of non-user, discomfort, pain, and user's satisfaction. For technical measures, good socket fit, malalignment, insufficient craftsmanship, and replacement were included. There are many studies reported the factors related to usage, functional outcomes, satisfaction, and quality of life. van Brakel WH and colleagues reported that causes of amputation, servicing center, type of the components, and problems after receiving the prosthesis were related to satisfaction.⁽³⁾ In addition, living environment, gait aids, type of prosthesis, a spare prosthesis, good socket fit, need for replacement, and patient's satisfaction were related to usage.⁽³⁾ Pohjolainen T and Alaranta H reported age and level of amputation as predictive factors for walkability.⁽⁶⁾ In Thailand, Pumpitakkul reported the time after surgery to

Correspondence to: Woratee Dacharux, MD, FRCPhysiatrT; Department of Anatomy, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand; E-mail: woratee.dah@mahidol.edu

Received: 8th June 2020

Revised: 2nd July 2020

Accepted: 27th September 2020

prosthesis fitting but not the relationship of it to usage.⁽⁷⁾ Thirapatarapong W and Dajpratham P reported the use of prosthesis and factors related to the use but not included technical measures, not specific to trans-tibial prosthesis, and the center of service.⁽⁸⁾ Ananub K reported the duration of manufacturing time for both trans-femoral and trans-tibial prosthesis.⁽⁹⁾ To the authors' knowledge, there was no research studying prosthesis service and servicing factors related to the use of prosthesis, reported from a school of prosthetics and orthotics in Thailand.

Sirindhorn School of Prosthetics and Orthotics (SSPO), Faculty of Medicine Siriraj Hospital, Mahidol University is the only prosthetics and orthotics school in Thailand. There are about 130 to 160 trans-tibial prostheses delivered each year. Making a trans-tibial prosthesis requires a lot of resources including money, time, and manpower. The cost of a trans-tibial prosthesis is about 30,000 Baht and it takes about four weeks or more for production. To ensure the resources are not wasted and the amputees do benefit from the prostheses, identifying and improving significant factors are worth considering. The aim of the present study was to identify servicing outcomes and factors related to the use of prostheses.

Methods

The present study was approved by Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, reference number 348/2563(IRB4), certification number 415/2020.

Participants

Amputees received trans-tibial prosthesis from the Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital, Mahidol University during May 2019 - February 2020.

Inclusion criteria were having K-level K1-K4, receiving the prosthesis and completing follow-up appointments, and using the current prosthesis for at least one month after the delivery

Exclusion criteria were having incomplete information in the medical record or SSPO follow-up form and prostheses made by students.

Sample size calculation

A study done by Jensen JS reported the percentage of trans-tibial prostheses use of 93%.⁽⁵⁾ Based on a power of 0.90 to detect a significant difference (5% type I error and 10% type II error, $p = 0.05$, two-sided), 25 participants were required. Due to the nature of study design, 20% of drop-off was estimated. The recruited sample size should be at least 30 subjects in total.

Study protocol

The SSPO follow-up forms were reviewed to exclude duplication and cases served by students. Information

retrieved from the follow-up forms and the medical records without identifiable information were collected and recorded into an encrypted digital file only. Information retrieved from medical records were age, gender, cause of amputation, side of amputation, underlying disease/condition, stump length, stump complication, expected K-level, servicing prosthetist, number of the previous prostheses, designs of the previous and the current prostheses, dates of each provision process, and physical therapy received.

From the follow-up form, date of follow-up, number of days in a week that the prosthesis was used, problems reported by the patients, and comments and adjustments by prosthetist, were identified and recorded.

Definitions

Weakness was defined if either stated in the medical records or motor power grade less than 5 in any muscle of the lower extremities.

Component change of the current prosthesis was defined as a change of any prosthetic component from the previous prosthesis.

First-time user was an amputee whose current prosthesis was the first one.

Stump length was classified by the ratio of the stump length to the sound leg length or the calculated length if the amputee had bilateral amputation. The stump is short if its length is shorter than 30% and medium if it is 30%-66%.

The servicing prosthetist who had experience more than or equal to 3 years was classified as senior and who had less was classified as junior.

Doctor check was referred to a physiatrist who involved at the fitting and/or the delivering processes.

Physical therapy received was classified as pre- or post- by date of delivery.

Problems were classified as pain or discomfort.

For the causes of the problems socket misfit and malalignment, were derived from the doctors' or the prosthetists' notes. Unexpected component degradation was defined as any degradation or a problem of any component with manufacturing defect. Insufficient craftsmanship was defined if the prosthesis needed a minor adjustment such as smoothing of the socket brim, and not classified into any of the socket misfit, malalignment, nor unexpected component degradation. Disease natural course was defined if the stump shrank during the very first period after amputation. Patient's misunderstanding was defined if problems occurred from the patient's misunderstanding of how to don/doff the prosthesis or how to take care the stump.

Remaking was defined if the prosthetist decided to recast the socket.

Statistical analysis

Statistical analyses were performed with the Statistical Package for Social Sciences (SPSS Inc, Chicago, IL, USA)

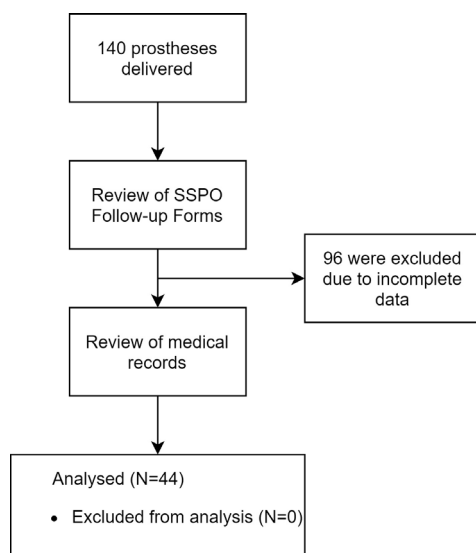


Figure 1. Flow diagram of the study

version 18.0. A p -value of less than 0.05 was considered a statistically significant difference.

For the main outcome, the use of prosthesis, the participants were divided into daily-user and non-daily-user groups. The number of the participants who used the prosthesis for 0, 1-3, and 4-6 days a week were combined to non-daily-user group. For the variable causes of amputation, the causes other than trauma were combined into non-trauma. The participants who had no previous prosthesis before the prosthesis under review were classified as first-time users. The servicing prosthetists who had experience more than three years were classified as senior, and those who had less as junior. The duration from surgery to prescription date was used only for the first-time users.

Demographic data was shown in frequency table as counts and percentage. Kolmogorov–Smirnov test was used to test normality of the continuous data. Means, inter-quartile range (IQ), and 95% confidence intervals (95%CI) as summary measures for normally-distributed and median, minimum, and maximum for non-normally-distributed data were used.

Unpaired t-test and Mann–Whitney test were used to analyze the differences of quantitative data with normal distribution and non-normal distribution, respectively. Fisher's exact test and Pearson's chi-squared test were performed to analyze the differences of categorical data. Multiple logistic regression analysis was used to find associations between possible variables and the main outcome. The resulting odds ratios (OR) show the amplitude of association, OR more than 1 indicates the increased likelihood of daily use and OR less than 1 indicates the decreased likelihood. To find cut-off value, receiver operating characteristic (ROC) analysis was used and the point where the sensitivity and specificity of the test are equal was selected.

Results

Ninety-six patients were excluded, hence there were 44 participants in total; the median age was 56 (range 2-82) and 28 were men (63.6%) (Table 1). Almost all needed only one prosthesis (88.6%). The majority of the participants had underlying disease (68.2%) such as diabetes, vascular diseases, or else. Around half of the participants had at least one of stump complications (54.5%) prior to the study either stump pain, skin hypersensitivity, stump volume fluctuation, wound, or contracture. Of all available stump length data, medium length was commonly found (55.56%). Community ambulation (K-level 2 and 3) was mostly expected (81.8%). About one-third were prosthesis first-time users. Around two-third had the same current prosthesis designs as the previous one. The numbers of prostheses made by junior and senior

Table 1. Characteristics of all 44 participants

Variables	Frequency	Percentage
Age ¹	56	(2, 82)
Gender		
Male	28	63.6
Female	16	36.4
Causes of amputation or limb loss		
N/A	1	2.3
Trauma	18	40.9
Vascular	8	18.2
Cancer	2	4.5
Congenital	3	6.8
Infection	12	27.3
First-time user	15	34.1
Underlying diseases*		
None	14	31.8
Diabetes mellitus	15	34.1
Vascular	11	25
Others	23	52.3
Bilateral amputation	5	11.4
Expected K-level		
1	7	15.9
2	15	34.1
3	21	47.7
4	1	2.3
Stump length		
N/A	8	18.2
Medium	20	45.5
Short	16	36.4
Weakness	7	15.9
Stump complications*		
None	20	45.5
Scar adhesion	1	2.3
Hypersensitivity	6	13.6
Volume fluctuation	3	6.8
Pain	16	36.4
Wound	6	13.6
Contracture	5	11.4

¹Median (min, max); N/A, not available

*Some participants had more than one underlying disease or stump complication

certified prosthetists were equal. About one-third of the prostheses were checked by psychiatrists on the fitting date. Around forty percent received physical therapy. For the first-time users, the mean duration from the date of surgery to the date of prostheses prescription was 228 (interquartile range 89, 322) days. For all participants, the mean durations of prescription-to-casting, casting-to-fitting, and fitting-to-delivery were 53, 22, and 20 days, respectively. (Table 2.)

After receiving the prostheses, 68.2% had prosthesis-related problems; discomfort (50%) and pain (27.3%). The causes of the problems were socket misfit (31.8%), malalignment (13.6%), insufficient craftsmanship (15.9%), unexpected degradation of the component (4.5%), natural course of the disease (6.8%), and patient's misunderstanding (9.1%). These required remaking in 4.5% and revisiting (by the end of data collection) in 29.5% of all participants. (Table 2.)

Regarding the use of prosthesis, there were 29 (65.9%) daily users. Comparing between daily and non-daily users, the daily users statistically significantly received the prosthesis from junior prosthetists and had less time between casting and fitting ($p = 0.026$ and 0.006 , respectively). (Table 3) When using multivariate logistic regression analysis, the only factor associated with daily use of the prosthesis was duration between casting and fitting day. Those who waited between these two processes less than 21 days had 5.4 times more chance to use the prosthesis every day than who waited for longer (odds ratio = 5.4, 95% CI 1.3-22.7). (Table 4.)

Discussion

There was no consensus yet at which level of usage the patient should be defined as user. Some other studies used the number of hours per day to categorize users.^(3,8) The present study included patients with expected K-level from K1 to K4 and as high as around one-third of them used the prostheses for the first time (34.1%) in particular. With these regards, it seemed unusual to expect equal time per day between the first-timer and the experienced users or K1 and K4 users. Therefore, the present study used number of days a week to categorize the participants. The result shows high rate of prosthesis use especially in every-day category as 65.9%. This finding was correlated well with such of other studies because trans-tibial amputation itself is one of the factors predicting successful prosthetic rehabilitation.^(3,8) Comparing daily-users to non-daily-users, there was no statistically significant difference for causes of amputation, underlying diseases, prior stump complications, component change from the previous prosthesis, physical therapy prior or after the casting, and even problems after receiving the prosthesis. Other studies also found the same trend for some variables but for the others perhaps due to participant's demographic heterogeneity. The present study involved more ageing people (median age = 56 years) who had at

Table 2. Characteristics of the prostheses and the service provision

Variable	Frequency	Percentage
Socket		
PTB	13	29.5
PTB + thigh corset	1	2.3
PTB-SC	29	65.9
TSB	1	2.3
Liner		
Foam	36	81.8
Silicone	5	11.4
Silicone with Foam	3	6.8
Suspension		
Self-suspension	25	56.8
Sleeve	2	4.5
Supra-patella cuff	15	34.1
Thigh corset	2	4.5
Shank		
Endoskeletal	31	70.5
Exoskeletal	13	29.5
Foot		
SACH	34	77.3
Single-axis	7	15.9
Dynamic	3	6.8
Change of component from the previous prosthesis		
N/A	1	2.3
Yes	12	27.3
No	31	70.5
Servicing prosthetist		
Senior	25	56.8
Junior	19	43.2
Doctor check	17	38.6
Physical therapy*		
None	27	61.4
Pre	8	18.2
Post	16	36.4
Duration(days) ¹		
Surgery to prescription**	228	(89, 322)
Prescription to casting	53	(28.3, 84.5)
Casting to fitting	22	(16, 24)
Fitting to delivery	20	(6.25, 25.3)
Using-days per week		
0	2	4.5
1-3	4	9.1
4-6	9	20.5
7	29	65.9
Prosthesis-related problems*		
None	14	31.8
Discomfort	22	50
Pain	12	27.3
Causes of problems		
Socket misfit	14	31.8
Malalignment	6	13.6
Insufficient craftsmanship	7	15.9
Unexpected component degradation	2	4.5
Disease natural course	3	6.8
Patient's misunderstanding	4	9.1
Remaking	2	4.5
Number of revisiting for prosthetic services		
1 time	5	11.4
2 times	5	11.4
3 times	2	4.5
5 times	1	2.3

¹Mean (interquartile range); *Some participants have both pre-delivery and post-delivery physical therapy or have more than one problem

**N = 15; N/A, not available; PTB, patellar tendon bearing; SC, supracondylar; TSB, total-surface-bearing; SACH, solid ankle cushion heel

Table 3. Comparisons of participants' characteristics between daily-users and non-daily users

Variables	Daily-users (n=29)	Non-daily-users (n=15)	p-value
Age ¹	59 (43, 66)	56 (53, 62)	0.88 ^a
Gender ²			
Male	17 (58.6)	11 (73.3)	0.34 ^b
Causes ²			
Trauma	12 (66.7)	6 (33)	0.37 ^b
First-time user ²			
Yes	9 (31)	6 (40)	0.6 ^b
Underlying disease ^{2,*}			
None	11 (37.9)	3 (20)	0.31 ^c
Diabetes mellitus	9 (31)	6 (40)	0.55 ^b
Vascular	7 (24.1)	4 (26.7)	1 ^c
Others	14 (48.3)	9 (60)	0.46 ^b
Bilateral amputation ²			
Yes	2 (6.9)	3 (20)	0.3 ^c
Expected K-level ²			0.82 ^b
1	4 (13.8)	3 (20)	
2	12 (41.4)	3 (20)	
3	12 (41.4)	9 (60)	
4	1 (3.4)	0 (0)	
Stump length ²	(n=23)	(n=13)	0.88 ^b
Medium	13 (56.5)	7 (53.8)	
Short	10 (43.5)	6 (46.2)	
Lower limb weakness ²	6 (20.7)	1 (6.7)	0.393 ^c
Stump complications ²			
Yes	15 (51.7)	9 (60)	0.6 ^b
Change of component from the previous prosthesis ²			
Yes	9 (31)	3 (20)	0.534 ^b
Servicing prosthetist ²			
Senior	13 (44.8)	12 (80)	0.03 ^b
Junior	16 (55.2)	3 (20)	
Doctor check ²			
Yes	13 (4.8)	4 (26.7)	0.24 ^b
Physical therapy ^{2,*}			
None	18 (62.1)	9 (60)	0.89 ^b
Pre-delivery	5 (17.2)	3 (20)	1 ^c
Post-delivery	10 (34.5)	6 (40)	0.456 ^b
Duration (days) ¹			
Surgery to prescription ^{**}	127 (101, 147)	217 (89, 348)	0.72 ^a
Prescription to casting	46 (33, 85)	29 (21, 44)	0.13 ^a
Casting to fitting	17 (15, 20)	24 (19, 28)	0.01 ^a
Fitting to delivery	12 (7, 26)	8 (5.5, 19)	0.35 ^a
Casting to fitting duration (days) ^{1,2}			
> 21 days	17 (15, 20)	24 (19, 28)	0.01
< 21 days	7 (24.1)	10 (66.7)	0.01 ^b
< 21 days	22 (75.9)	5 (33)	
Prostheses-related problems ^{2,*}			
None	10 (34.5)	4 (26.7)	0.74 ^b
Discomfort	13 (44.8)	9 (60)	0.34 ^b
Pain	7 (24.1)	5 (33.3)	0.72 ^c
Causes of prostheses-related problems ^{2,*}			
Socket misfit	8 (27.6)	6 (40)	0.5 ^c
Malalignment	4 (13.8)	2 (13.3)	1 ^c
Insufficient craftsmanship	7 (24.1)	0 (0)	0.08 ^c
Unexpected component degradation	1 (3.4)	1 (6.7)	1 ^c
Disease natural course	3 (10.3)	0 (0)	0.5 ^c
Patient's misunderstanding	0 (0)	4 (26.7)	0.01 ^c
Remaking ²			
Number of revisiting ²			
0 time	1(3.4)	1(6.7)	1 ^c
1 time	21 (72.4)	10 (66.7)	0.37 ^b
2 times	3 (10.3)	2 (13.3)	
3 times	4 (13.8)	1 (6.7)	
4 times	1 (3.4)	1 (6.7)	
5 times	0 (0)	1 (6.7)	

¹Median (interquartile range); ²mean (interquartile range); ^aMann-Whitney test; ^bPearson Chi-Square; ^cFisher's Exact test

*Some participants had more than one underlying disease, problem and the cause of the problem, or received both pre-delivery and post-delivery physical therapy; **n=15

Table 4. Factors associated to prosthesis daily-use

Variables	Crude OR (95% CI)	Adjusted OR (95% CI)	p-value
Servicing prosthetist			
Senior	1.0	1.0	0.075
Junior	4.9 (1.1-21.2)	4.1 (0.9-19.5)	
Casting to fitting duration			
> 21 days	1.0	1.0	0.020
< 21 days	6.3 (1.6-25)	5.4 (1.3-22.7)	

OR, Odds ratio; CI, Confident interval

p-value from Enter method, Binary Logistic Regression Analysis

least one underlying disease (68.2%). Two variables found statistically significant difference were servicing prosthetist being less experienced (junior) and less duration from casting to fitting day.

For servicing prosthetists, the authors categorized prosthetists who had been working for more than 3 years by the time of the study as senior and who had less as junior. Because making a prosthesis requires skills and experience,⁽¹⁰⁻¹²⁾ the authors also hypothesized the prostheses made by more experienced prosthetist would give better outcomes, translated to more frequently used. The result turned out vice versa. Subgroup analysis comparing junior and senior prosthetists was done. Even though, statistical significance was not found for the conditions of the participants and the problems after receiving the prosthesis, there was a trend in different causes of amputation and the duration the prosthetists spent in each process. The senior prosthetists served more non-trauma cases and spent more time in each process. These two factors might indicate the cases served by the senior prosthetists were more complicated than those by the junior, however, is not the extent of the present study.

For casting to fitting duration, this was the only factor related to the daily use of the prosthesis after multivariate logistic regression analysis. Socket fit has long been widely known as one of the most significant factors contributed to prosthesis use level and satisfaction.^(5,13-19) Although, socket misfit was found not statistically significant in the present study ($p = 0.5$). Less waiting time after casting can be transferred to less chance of condition changes either the stump or the other parts of the body and also expectation of the users.^(20,21) The present study found cut-off value for this variable was 21 days. By achieving appointing the patient for fitting in less than 21 days from the casting date increases 5.4 times likelihood the patient will use the prosthesis daily than those who cannot. From the authors' opinion, this cut-off duration is sensible especially in the first-time user because this duration is within the period which the stump loses its volume the greatest.⁽²²⁾ Moreover, it is possible by most of the prosthesis service centers even in secondary hospital.^(9,23) These technical processes management should be paid more attention on for the best to the patients.

In contrary, the high use rate found in the present study, which is a patient-reported outcome, is not concur with the

technical-assessed problems (discomfort, pain; $p = 0.34$, 0.72 respectively). There is possibility the present study might have a bias toward daily user group. The authors hypothesize three possible factors. First, the participants included must completed following-up. Those who did not use the prostheses might refuse the follow-up. Second, a trans-tibial prosthesis costs high amount of money if self-paid. Considering Thailand is a middle-to-high income country and a prosthesis is covered by the disabled rights, the participants might accept a level of problems in exchange to be given it for free.⁽²⁴⁾ Third, even with high rate of problems found, there were quite low rate of remaking (4.5%) and patient revisiting (29.1%) which were less than some other studies.^(5,13) This reflects the problems could be minor and not related to daily-use ($p = 1$, 0.37 respectively).

To our knowledge, the present study is the first study in Thailand reporting the prosthesis use and relating factors with regard to technical variables. Thirapatarapong W. and Dajpratham P. reported the use of all type of prostheses as high as 82.1% and the factors related to the use; less diabetes mellitus, being younger at the time of amputation, employed status, satisfaction to good wearing comfort, a trans-tibial level of amputation, and undergoing particular etiologies of amputation such as congenital problem or blast injury.⁽⁸⁾ All those are patient-related outcomes. Since the study was a postal survey, assessing technical and follow-up information could be difficult. To improve the quality of the devices provided and service, another aspect of information which is specific to a type of device and servicing center might avail.

ISPO established quality benchmark for trans-tibial prostheses in low-income countries in 2005.⁽⁵⁾ The technical performance demands were set for good socket fit at $60 \pm 10\%$, misalignment at $15 \pm 10\%$, insufficient craftsmanship at $10 \pm 10\%$, and requirements for socket change at $10 \pm 10\%$. Comparing to those of the present study were 68.2% (100 – socket misfit%), 13.6%, 15.9%, 4.5% respectively, all were within ranges. These are comparable to the result W. Van Brakel reported of good socket fit at 61%, poor alignment at 11.4%, and socket replacement at 7.4%.⁽³⁾ In another aspect, the patient compliance demands were set for discomfort at $10 \pm 10\%$, pain at $10 \pm 10\%$, and non-users at $5 \pm 5\%$. Pain and discomfort in the present study were found far more than the benchmark ranges and in other studies.^(3,5,13) These two measures are quite difficult to compare since they are patient-reported outcomes. The present study set pain and discomfort as a result of any technical problems, not only reported by the participants. Observed from the results of the other studies, the numbers of reported pain and discomfort were not equal to those of problems found.^(3,13) Different inclusion measure is suspected. For non-user outcome, only two participants (4.5%) reported as non-users which is within the benchmark range.

The present study had some limitations. Because of the retrospective study in nature, the completeness of data was the major limitation. Only around one-third were recruited despite many delivered prostheses. Number of participants was also a limitation. Although the number of recruited participants met the calculated sample size, more number could show more outcomes related to the use. In Thailand, every registered amputee is given a prosthesis for free every one-year period. All the participants used the disabled right. If the recruiting period is more than a year, the authors expected some amputees who come more than once. Because of this, the nature of the study, and the COVID-19 situation during the time of study, not so many participants were recruited. Lastly, the present study focuses more on service provision and technical outcomes. There were other patient-reported outcomes reported elsewhere but not included in the present study such as user's satisfaction, the environment the prosthesis is used, walking aid use, spare prosthesis, age at time of amputation, employment status, and wearing comfort. In addition, functional capability, participation, and quality of life are all important and parts of reflecting further benefit of prostheses.⁽²⁵⁻²⁹⁾ These factors should be encouraged to be included in future study and clinical assessment.

In conclusion, most patients used the prosthesis every day regardless to the problems occurred. Problems were found in the majority of the devices provided but the consequences were minor. The only factor related to the every-day prosthesis use was the duration from casting to fitting day. Cut-off duration from casting to fitting day was 21 days.

Disclosure

The authors declare no conflict of interest of any kind.

Acknowledgments

Suthipol Udompunterak, MSc. (Applied Statistics) Research Department, Faculty of Medicine Siriraj Hospital, Mahidol University

References

- National Statistical Office [internet]. Bangkok: National Statistical Office, Thailand. 2012 - [cited 2020 May 28]. Available from: <http://www.nso.go.th/sites/2014/Pages/%E0%B8%AA%E0%B8%B3%E0%B8%A3%E0%B8%A7%E0%B8%88%E0%B8%94%E0%B9%89%E0%B8%B2%E0%B8%99%E0%B8%AA%E0%B8%B1%E0%B8%87%E0%B8%84%E0%B8%A1%E0%B8%AA%E0%B8%A7%E0%B8%B1%E0%B8%AA%E0%B8%94%E0%B8%B4%E0%B8%81%E0%B8%B2%E0%B8%A3%E0%B8%AA%E0%B8%B1%E0%B8%87%E0%B8%84%E0%B8%A1%E0%B8%84%E0%B8%A7%E0%B8%B2%E0%B8%A1%E0%B8%9E%E0%B8%B4%E0%B8%81%E0%B8%B2%E0%B8%A3.aspx>.
- Hordacre BG, Stevermuer T, Simmonds F, Crotty M, Eagar K. Lower-limb amputee rehabilitation in Australia: analysis of a national data set 2004-10. *Aus Health Rev.* 2013;37:41-7.
- Van Brakel W, Poetsma PA, Tam PT, Verhoeff T. User satisfaction and use of prostheses in ICRC'S special fund for the disabled project in Vietnam. *Asia Pacific Disabil.* 2010;21:70-91.
- National Statistical Office [internet]. Bangkok: National Statistical Office, Thailand. 2017. [cited 2020 May 28]. Available from: <http://www.nso.go.th/sites/2014/Pages/%E0%B8%AA%E0%B8%B3%E0%B8%A3%E0%B8%A7%E0%B8%88%E0%B8%94%E0%B9%89%E0%B8%B2%E0%B8%99%E0%B8%AA%E0%B8%B1%E0%B8%87%E0%B8%84%E0%B8%A1%E0%B8%AA%E0%B8%A7%E0%B8%B1%E0%B8%AA%E0%B8%94%E0%B8%B4%E0%B8%81%E0%B8%B2%E0%B8%A3%E0%B8%AA%E0%B8%B1%E0%B8%87%E0%B8%84%E0%B8%A1%E0%B8%84%E0%B8%A7%E0%B8%B2%E0%B8%A1%E0%B8%9E%E0%B8%B4%E0%B8%81%E0%B8%B2%E0%B8%A3.aspx>.
- Jensen JS, Nilsen R, Zeffner J. Quality benchmark for trans-tibial prostheses in low-income countries. *Prosthet Orthot Int.* 2005;29:53-8.
- Pohjolainen T, Alaranta H. Predictive factors of functional ability after lower-limb amputation. *Ann Chir Gynaecol.* 1991;80:36-9.
- Pumpitakkul K SC, Sirisabya P. The follow up study in usage of lower limb prosthesis in Police General Hospital 1999. *J Thai Rehabil.* 2000;10:7.
- Thirapatarapong W, Dajpratham P. Prosthetic usage among the Thai lower limb amputees. *Siriraj Med J.* 2009;61:185-8.
- Anannub K. Study the duration of producing lower extremity prostheses and the satisfaction of patients. *Med J Srisaket Surin Buriram Hosp.* 2019;34:303-11.
- Boone DA, Kobayashi T, Chou TG, Arabian AK, Coleman KL, Orendurff MS, et al. Perception of socket alignment perturbations in amputees with transtibial prostheses. *J Rehabil Res Dev.* 2012;49:843-53.
- Chen CWJ, Heim W, Fairley K, Clement RJ, Biddiss E, Torres-Moreno R, et al. Evaluation of an instrument-assisted dynamic prosthetic alignment technique for individuals with transtibial amputation. *Prosthet Orthot Int.* 2015;40:475-83.
- Polliack AA, Craig DD, Sieh RC, Landsberger S, McNeal DR. Laboratory and clinical tests of a prototype pressure sensor for clinical assessment of prosthetic socket fit. *Prosthet Orthot Int.* 2002;26:23-34.
- Jensen JS, Raab W, Fisk J, Hartz C, Saldana A, Harte C. Quality of polypropylene sockets for trans-tibial p in low-income countries. *Prosthet Orthot Int.* 2006;30:45-59.
- Colombo G, Filippi S, Rizzi C, Rotini F. A new design paradigm for the development of custom-fit soft sockets for lower limb prostheses. *Comput Ind.* 2010;61:513-23.
- Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. *Disabil Rehabil.* 2003;25:1278-80.
- Carroll K. Options in sockets and liners options. In *Motion Mag.* 2009;19:19-22.
- Marks LJ, Michael JW. Science, medicine, and the future: artificial limbs. *BMJ.* 2001;323:732-5.
- Mohd Hawari N, Jawaid M, Md Tahir P, Azmeer RA. Case study: survey of patient satisfaction with prosthesis quality and design among below-knee prosthetic leg socket users. *Disabil Rehabil Assist Technol.* 2017;12:868-74.
- Paterno L, Ibrahim M, Gruppioni E, Menciassi A, Ricotti L. Sockets for limb prostheses: a review of existing technologies and open challenges. *IEEE Trans Biomed Eng.* 2018;65:1996-2010.
- Murray CD. Being like everybody else: the personal meanings of being a prosthesis user. *Disabil Rehabil.* 2009;31:573-81.
- Sanders JE, Fatone S. Residual limb volume change: systematic

- review of measurement and management. *J Rehabil Res Dev.* 2011;48:949-86.
22. Lilja M, Hoffmann P, Oberg T. Morphological changes during early trans-tibial prosthetic fitting. *Prosthet Orthot Int.* 1998;22:115-22.
 23. O'Keeffe B, Rout S. Prosthetic rehabilitation in the lower limb. *Indian J Plast Surg.* 2019;52:134-43.
 24. Ikeda AJ, Grabowski AM, Lindsley A, Sadeghi-Demneh E, Reisinger KD. A scoping literature review of the provision of orthoses and prostheses in resource-limited environments 2000-2010. Part two: research and outcomes. *Prosthet Orthot Int.* 2014;38:343-62.
 25. Dajpratham P, Tantiramai S, Lukkanapichonchut P. Health related quality of life among the Thai people with unilateral lower limb amputation. *J Med Assoc Thai.* 2011;94:250-5.
 26. Davie-Smith F, Coulter E, Kennon B, Wyke S, Paul L. Factors influencing quality of life following lower limb amputation for peripheral arterial occlusive disease: a systematic review of the literature. *Prosthet Orthot Int.* 2017;41:537-47.
 27. Foote CE, Kinnon JM, Robbins C, Pessagno R, Portner MD. Long-term health and quality of life experiences of Vietnam veterans with combat-related limb loss. *Qual Life Res.* 2015;24:2853-61.
 28. Hawkins AT, Pallangyo AJ, Herman AM, Schaumeier MJ, Smith AD, Hevelone ND, et al. The effect of social integration on outcomes after major lower extremity amputation. *J Vasc Surg.* 2016;63:154-62.
 29. Peters CML, de Vries J, Lodder P, Steunenbergh SL, Veen EJ, de Groot HGW, et al. Quality of life and not health status improves after major amputation in the elderly critical limb ischaemia patient. *Eur J Vasc Endovasc Surg.* 2019;57:547-53.