Compliance and satisfaction of lower limb amputees toward basic prostheses

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Background   :   *King Chulalongkorn Memorial Hospital (KCMH) has been providing prosthetic services for more than 30 years. Due to the financial limitation of patients, most of the components prescribed for the lower limb prostheses were conditioned by the National Insurance allowance. These basic components have limitation regarding biomechanical properties that do little to restore the complex biomechanics of human walking, especially among patients, who are routinely active in daily life or need prostheses to work.*

Objective   :   *To explore compliance and satisfaction of lower limb amputees toward prostheses.*

Study Design   :   *Descriptive and analytical study.*

Setting   :   *Prosthetic-Orthotic (PO) Unit, Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital (KCMH).*

Subjects   :   *Lower extremity amputees who received prostheses from the PO Unit, KCMH.*

Method   :   *Patients' records were reviewed. Amputees who met the criteria were contacted by phone and recruited into the study. Interviews were conducted at KCMH. Data collection was performed including demographic data, details of amputation, prosthetic device and its component, usability in daily living and the satisfaction with the prostheses and the service. Data analysis was performed by computerized statistical program.*

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Results   :   *Thirty lower limb amputees were recruited into the study. Their average age was 60 years old and 60% of them were male. The majority were below knee amputees (27 patients, 90%). A total of 76.7% of the subjects were still using prostheses in their daily activities; 80% of the amputees graded the satisfaction level as "satisfied" or "most satisfied". The factor that was significantly related to subjects' satisfaction regarding the prosthetic devices and PO Unit services was the K-level. (P = 0.001, 0.002, respectively).*

Conclusion   :   *A total of 76.7% of lower limb amputees were still using the prostheses in daily activities. The majority (80%) had good and very good levels of satisfaction. This means the prostheses with basic components can generally be used by amputees with relatively good results. The K-level was significantly associated with satisfaction level. Thus, doctors and prosthetists should focus on explaining the objective and possibility of using the prostheses, which was correlated to K-level for individual patients. This could encourage using the prosthesis in individual patient's functional capacity and also improve patient's satisfaction.*

Keywords   :   *Amputee, K-level, lower limb prostheses, patient satisfaction.*

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เหตุผลของการทำวิจัย : โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย ได้ให้บริการทำขาเทียมแก่ผู้ป่วยขาขาดมานานกว่า 30 ปี เนื่องด้วยข้อจำกัดด้านการเงินและราคาของอุปกรณ์ ทำให้ผู้ป่วยที่มารับบริการส่วนใหญ่ได้รับขาเทียมที่มีส่วนประกอบแบบพื้นฐานตามเกณฑ์การเบิกจ่ายตามสิทธิการรักษาพยาบาล ซึ่งส่วนประกอบของขาเทียมแบบพื้นฐานนี้มีคุณสมบัติทางชีวกลศาสตร์ที่จำกัด และไม่สามารถทดแทนการเคลื่อนไหวของขาและเท้า หรือทดแทนรูปแบบการเดินที่ซับซ้อนของมนุษย์ได้

วัตถุประสงค์ : เพื่อศึกษาการใช้ประโยชน์และความพึงพอใจในการใช้งาน และปัจจัยที่เกี่ยวข้องต่อขาเทียมในผู้ป่วยตัดขา

รูปแบบงานวิจัย : วิจัยเชิงพรรณนาและเชิงวิเคราะห์

สถานที่ทำวิจัย : หน่วยกายอุปกรณ์ ฝ่ายเวชศาสตร์ฟื้นฟู โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย

กลุ่มประชากร : ผู้ป่วยตัดขาและได้รับกายอุปกรณ์เทียมจากฝ่ายเวชศาสตร์ฟื้นฟู โรงพยาบาลจุฬาลงกรณ์

วิธีการศึกษา : ทบทวนเวชระเบียนและบันทึกของหน่วย และคัดเลือกรายชื่อผู้ป่วยที่ได้รับขาเทียม ตามเกณฑ์คัดเข้าและออก ติดต่อผู้ป่วยทางโทรศัพท์เพื่อเชิญเข้าร่วมโครงการ และเชิญมาเพื่อสัมภาษณ์ และเก็บข้อมูลที่โรงพยาบาลจุฬาลงกรณ์ โดยบันทึกข้อมูลพื้นฐาน, ข้อมูลเกี่ยวกับการตัดขา, การเข้ารับบริการที่หน่วยกายอุปกรณ์, การใช้ งานขาเทียมจริงในชีวิตประจำวัน และความพึงพอใจต่อขาเทียม และการบริการ และนำมาวิเคราะห์ข้อมูลทางสถิติ

ผลการศึกษา : ผู้ป่วยตัดขาที่เข้าร่วมงานวิจัยจำนวน 30 ราย อายุเฉลี่ย 60 ปี เป็นผู้ชาย 18 ราย (ร้อยละ 60) ได้รับการตัดขาระดับใต้เข่า 27 ราย (ร้อยละ 90) พบว่าผู้ป่วยที่ใช้งานขาเทียมจริงในชีวิตประจำวันมีจำนวน 23 ราย (ร้อยละ 76.7) ผู้ป่วยมีความพึงพอใจในขาเทียมระดับมากถึงมากที่สุดคิดเป็นร้อยละ 80 เมื่อศึกษาถึงปัจจัยที่ส่งผลต่อระดับความพึงพอใจของผู้ป่วย พบว่าระดับ K-level มีความสัมพันธ์เชิงบวกกับระดับความพึงพอใจในอุปกรณ์ขาเทียม และความพึงพอใจต่อการบริการของหน่วยกายอุปกรณ์ฯ แบบมีนัยสำคัญทางสถิติ ($P = 0.001$, $= 0.02$ ตามลำดับ)

สรุป   :   *ร้อยละ 76.7 ของผู้ป่วยใช้ขาเทียมจริงในชีวิตประจำวัน และร้อยละ 80*
มีความพึงพอใจต่อขาเทียมที่ได้รับระดับมากถึงมากที่สุด แสดงว่าผู้ป่วย
ตัดขาสามารถใช้งานและมีความพึงพอใจต่อขาเทียมแบบพื้นฐานใน
ระดับค่อนข้างดี ปัจจัยที่มีความสัมพันธ์ต่อความพึงพอใจของผู้ป่วย
คือระดับศักยภาพของผู้ป่วยในการใช้ขาเทียม (K-level) ซึ่งอาจเกิดได้
จากผู้ป่วยที่มีระดับ K-level ต่ำมีความคาดหวังต่อการใช้ขาเทียมที่ไม่
สอดคล้องกับการนำไปใช้จริง ดังนั้นจึงควรให้ความสำคัญในการให้
ความรู้และความเข้าใจที่ถูกต้องในการใช้ขาเทียมที่สอดคล้องกับระดับ
ศักยภาพจริงของผู้ป่วย

คำสำคัญ   :   *ผู้ป่วยตัดขา, กายอุปกรณ์เทียม, ขาเทียม, ความพึงพอใจของผู้ป่วย.*

Every year in Thailand, many patients need amputation surgery on various reasons. Most of the causes of amputation include accident, peripheral vascular disease, diabetes complication and malignancy. Amputation leads to limitation in movement and mobility of the patients and also affects patients' community participation and occupation, causing negative psychological effects on patients and their family members. Approximately, the number of amputees registered with The Thai National Health Care System is 46,000, and the Ministry of Public Health reported 3,500 patients had lower extremity amputation in 2007. Prosthetic service serves the most important roles in helping amputees' mobility and improving their quality of life. However, the cost of the prosthesis is expensive.

The Thai National Health Insurance supports a prosthetic component at the lowest basic and most fundamental need. The basic parts comprise SACH foot, exoskeletal shank, safety knee unit (for above knee amputation) socket and basic suspension system (cuff suspension or Silesian belt). These components have limited biomechanic properties and cannot fully restore complex motion of human walking. King Chulalongkorn Memorial Hospital (KCMH) has been providing treatment for many amputees. Most of them received the prostheses with basic components according to the National Insurance allowance. Therefore, many patients receiving basic prostheses experience difficulty when applying, and may stop using them. This situation may constitute wasted government expenditure because we could prescribe better prostheses that suit patients' requirements.

Many studies have explored the number of amputees receiving prostheses but could not use them in their daily lives and in their jobs and finally stopped using them.[1 - 5] Pezzin et al. [1] studied the satisfaction and usability of prostheses in the United States and reported 94.5% of amputees still used prostheses in daily life, an average of 71 hours weekly. However, 33% of amputees reported dissatisfaction with the prostheses in terms of stump fit and discomfort while wearing. Gauthier_Gagnon et al.[2] conducted a similar study in Canada and reported that 63% of amputees used prostheses in daily living activities and 53% wore prostheses in their homes. Moreover, above-knee amputees reported more difficulty in using their prostheses compared with below-knee amputees. Davidson et al. [3] studied upper extremity amputees in Australia and reported that only 56% of amputees used their prostheses not more than once then stopped using them. They also reported low to average levels of satisfaction, i.e., 64%.

A very limited number of studies in Thailand have explored the usability of prosthesis. In 1993, Ramathibodi Hospital,[6] reported 78 of amputees kept using the prescribed prosthesis and further investigated the factors that prevented amputees to continue using prostheses and found that socioeconomic aspects, travelling difficulty to the hospital and prosthetic discomfort were major causes. In 1998, the Police General Hospital [7] reported 100% use of prostheses from amputees in the hospital, but the subjects were 35 years old on average and 50% were police officers which did not represent the general characteristics of most amputees in Thailand, who were mostly elderly.

As reviewed, no research has been conducted on the usability and satisfaction levels concerning prostheses in Thailand for more than 20 years and a limited number of studies have explored

the usability of prostheses in Thailand, especially in KCMH. Therefore, the research team was determined to investigate the usability of prostheses, satisfaction levels of amputees and related factors. The data could be used to improve and develop the KCMH Prosthesis Unit including other government hospitals in Thailand. The objective of this study was to investigate the usability and levels of satisfaction of lower limb amputees toward the basic prosthesis.

Methods

The research employed a descriptive and analytic study design. The study sample comprised lower extremity amputees receiving prostheses from the Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital, Bangkok, Thailand.

Inclusion criteria were as follows; Lower extremity amputees who received prostheses from the Department of Rehabilitation Medicine, KCMH from 2000 to 2015, amputees who received prostheses at least 6 months before data collection, ability to communicate, and agreement to participate in the study.

Exclusion criteria were as follows; Inability to contact by phone, utility of other devices considered orthosis or prostheses in other parts of the body, inability to communicate or give valid information.

The study protocol was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University. (IRB number: 199/57) Medical data of patients receiving lower extremity prostheses were reviewed from the PO Unit, Department of Rehabilitation Medicine, KCMH and contact patients, who met the inclusion criteria, by

phone. The interview and physical examination were performed at KCMH, using the designed Case Record Form. The compliance and the detail of prosthetic use were reported by patients averagely 3 months' duration prior to interview date. The satisfaction level is determined by using numeric rating scale ranges from 1 to 5 which higher number defines more satisfaction level. The collected data were analyzed using statistical program.

Based on data from Pezzin *et al.* [1], the sample size was calculated using a confidence level of 95% and error <10%. A total sample size of 62 was indicated.

Statistical analysis was performed using the statistical program SPSS, version 22, the significance level (*P* value) < 0.05 was set.

Results

The study flow diagram shows 293 amputees, who received a prosthesis from the department. A total of 92 could be contacted by phone, of whom 30 amputees agreed to participate in the study.

Table 1. demonstrates demographic data from 30 subjects. Average age was 60 ± 14.8 years (60% were male). A total of 27 were below knee amputees and 3 were above knee amputees. Average weight and height were 66.5 ± 14.8 kg and 164.7 ± 8.0 cm, respectively. Mean BMI was 24.5 ± 4.7 kg/m^2. Categorizing for physical performance using the K-level classification[8] (detail of K-level is described in table 9), we found 17 subjects were at K3 level while our department never had K4 patient.

Table 2. shows details about amputation. The average age at the time of amputation surgery was 52.3 ± 16.0 years. Most indications for surgery were

from complications of diabetes (33.3%) and accidents (26.7%), respectively. The surgery was performed in KCMH for 73.3% of the patients who received the prosthesis at the PO Unit. Other 26.7% had amputation from other hospitals.
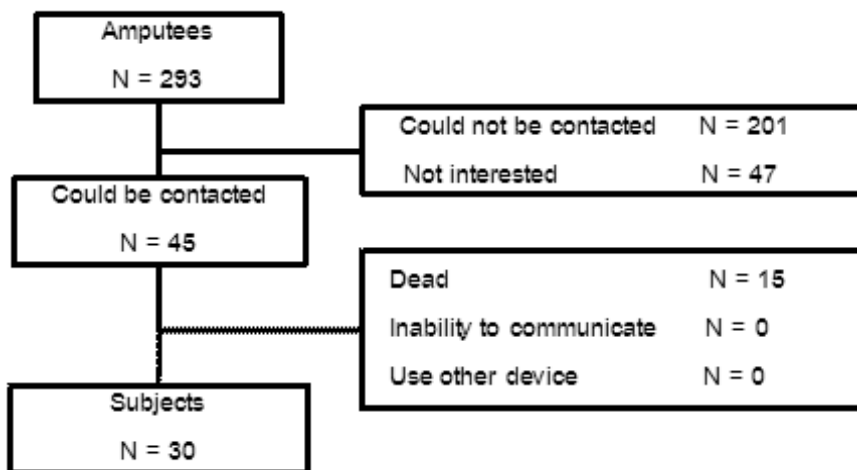

Figure 1. The study flow diagram.

Table 1. Demographic data (N = 30).

Characteristic	N (percent)	Mean (SD)
Sex		
Male	18 (60)	
Female	12 (40)	
Age (year)		60.1 (14.8)
Body mass index (kg/m^2)		24.5 (4.7)
Weight (kg)		65.5 (14.9)
Height (cm)		164.7 (8.0)
Place of stay (province)		
Bangkok	20 (33.3)	
Central part of Thailand	6 (20)	
Other provinces	4 (6.7)	
K-level		
K 0	4 (13.3)	
K 1	4(13.3)	
K 2	5 (16.7)	
K 3	17 (56.7)	
K 4	0 (0)	

Table 2. Amputation surgery details (N = 30).

Demographics	N (%)	Mean (SD)
Age at time of surgery (year)		52.3 (16.0)
Cause of amputation		
Diabetes and complications	10 (33.3)	
Accident	8 (26.7)	
Peripheral vascular disease	7 (23.3)	
Tumor and cancer	1 (3.3)	
Others	4 (13.3)	
Hospital that perform surgery		
KCMH	22 (73.3)	
Other hospitals	8 (26.7)	

Considering the use of prostheses in daily life activities, 23 subjects (76.7%) were still using their prostheses while another 7 had already stopped using their prostheses of which 6 stopped using the received prosthesis within 3 months of start date. The most common reasons reported were pain and discomfort while wearing (6 amputees) and difficulty of putting on and removing the prosthesis (5 amputees).

The data from 23 subjects, still using their prostheses (Table 3), show they needed to change to a new set of prostheses every 2 years on average. Subjects reported using prostheses 9.5 ± 6.3 hours daily on average and only 37% could remain in their previous occupations. However, 63% needed to change or adapt to their job or even quit doing working after amputation and receiving a prosthesis. Regarding repair of the device, 12 amputees reported they had their prosthesis repaired in the socket parts and 8 amputees had their prosthesis repaired in the suspension system.

Table 4. demonstrates the satisfaction levels of amputees. A total of 80% rated their satisfaction with prosthetic devices as satisfied to very satisfied levels. Further, 90% of amputees rated the satisfaction in treatment and PO Unit services as satisfied to very satisfied levels.

Concerning related factors described in Table 5, the K-level classification was a positive factor and significantly related to satisfaction level of amputees toward the prosthetic devices and the PO Unit service (P = 0.001, 0.02 respectively). And the status of using prosthesis (stopped using or still using the prosthesis) was also found to be significantly relate to satisfaction level of amputees toward the prosthetic devices. (P = 0.018) Table 6 – 8 describes into more detail about distribution of satisfaction level rating by amputees according to the mentioned factors.

Table 3. Details of using prosthesis in daily life activities (N = 23).

	N (%)	Mean	Median	Min	Max
Duration using the current set of prosthesis (month)		46.9	24	1	300
Number of prostheses used		4.65	2	1	7
Days per week of using prosthesis		6.9	7	5	7
Hours per day of using prosthesis		9.5	9	0.5	19
Hours per day of using prosthesis during work		4.24	3	0.5	13
Occupation status after amputation					
Same occupation	10 (37.0)				
Changed or adapted occupation	4 (14.8)				
Stopped working	8 (29.6)				
Repair of current prosthesis					
Has been repaired	18 (78.3)				
Never repaired	5 (21.7)				
Part of prosthesis broken down					
Foot	2 (8.7)				
Shank	6 (26.1)				
Socket	12 (52.2)				
Suspension system	8 (34.8)				

Table 4. Satisfaction level of amputees to related aspects (N = 30).

Satisfaction level	Least	Less	Moderate	More	Most
To prosthetic device	2	1	3	11	13
To medical or health care service	0	2	1	2	25
To PO Unit service	0	2	1	4	23

Table 5. Factors related to satisfaction level of amputees (N = 30).

Factors	Satisfaction level (*P* value)		
	Prosthetic device	**Medical service**	**PO Unit service**
Sex	0.323	0.271	0.384
Age	0.206	0.274	0.189
BMI	0.379	0.390	0.390
Residence	0.842	0.820	0.627
Age at amputation	0.717	0.834	0.719
Cause of amputation	0.638	0.725	0.676
Level of amputation	0.693	0.881	0.798
Hospital performing amputation	0.826	0.644	0.104
Physical performance, K-level	0.001*	0.053	0.021*
Status of using prosthesis	0.018*	0.562	0.370

* *P* < 0.05

Table 6. Association between K-level and satisfaction level of prosthetic device.

K-level	Satisfaction level of prosthetic device					Total
	Least	**Less**	**Moderate**	**More**	**Most**	
K 0	2	0	2	0	0	4
K 1	0	1	0	2	1	4
K 2	0	0	1	2	2	5
K 3	0	0	0	7	10	17
Total	2	1	3	11	13	30

Pearson's Chi-Square test: *P* = 0.001

Table 7. Association between K-level and satisfaction level of PO Unit service.

K-level	Satisfaction level of PO Unit service					Total
	Least	**Less**	**Moderate**	**More**	**Most**	
K 0	0	1	0	2	1	4
K 1	0	0	1	1	2	4
K 2	0	1	0	0	4	5
K 3	0	0	0	1	16	17
Total	0	2	1	4	23	30

Pearson's Chi-Square test: *P* = 0.021

Table 8. Association between status of using prosthesis and satisfaction level of prosthetic device.

Status of using the prosthesis	Satisfaction level of prosthetic device					Total
	Least	**Less**	**Moderate**	**More**	**Most**	
Stopped using	2	0	2	2	1	7
Still using	0	1	1	9	12	23
Total	2	1	3	11	13	30

Pearson's Chi-Square test: $P = 0.018$

Table 9. K-level: the classification of expected physical ability of amputees with prosthesis.

K-level	Description
K0	Does not have the ability or potential to ambulate with or without assistance. Prosthesis does not enhance their quality of life or mobility.
K1	Has the ability to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. - a typical limited or unlimited household ambulator.
K2	Has the ability for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces - a typical community ambulator.
K3	Has the ability for ambulation with variable cadence - a typical community ambulator with the ability to traverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic use beyond simple locomotion.
K4	Has the ability for prosthetic ambulation that exceeds basic ambulation skills. - typical of the prosthetic demands of children, active adults or athletes.

Discussion

From the results, we found that 76.7% of the amputees were still using their prostheses, but 23.3% had already stopped using them. This was comparable to the study of Ramathibodi Hospital [6] and the Police General Hospital[7] that reported a usability level of 73.4% and 78.1%, respectively. However, it was still lower than a study from the United States of America[1] that reported 94.5%. Amputees, still using their prostheses, reported 9.5 hours of use daily and using every day, which was also comparable with all previous studies.[6 - 7]

Regarding the issue of broken down prostheses, we found 78.3% of amputees had their prostheses repaired and the most common parts were the socket and suspension system. This differed from the study of Klaphajone et al. [9] that reported the most common broken down part was the foot (85%), but the socket was only 5%. We believe this occurred due to the differences in the materials, components and sources used to assemble the prostheses. We found the association of the status of using a prosthesis (still using and stopped using) was at a level of satisfaction similar to most studies.[1 - 4, 6 - 7,10]

Furthermore, this study demonstrates that K-level was a positive factor related to the level of satisfaction of the amputees. The researchers assumed the patients with low level of physical performance (low K-level) may have set their expectation too high regarding the received prosthesis and their own physical abiliy. This probably led to disappointment after using the prosthesis and experiencing the limitations to performing activities resulting from either the prosthesis itself, their own physical disabilities or both.

We recommend that healthcare personnel whose work are related to amputees and prosthesis should raise these concerns upon explaining the limitation of use of the prosthesis and the expected level of ability for particular amputees immediately before the start of prescribing the prosthesis to ensure the amputees or their relatives truly understand the goal of using the prosthesis and what level of activity or social participation they can expect to perform. This will lead to highersatisfactory levels.

Limitation

In this study, we could not recruit the number of subject as expected due to the limitations related to traveling to the hospital. We decided to conduct the study at the hospital rather than sending questionnaires by postal services as used in many studies because we expected a higher accuracy of the data collected by the researchers, which could be promptly clarified when needed. In addition, the researchers were also able to perform the basic physical examinations and recheck the prosthetic devices and their components. Previous studies also reported only a 40 to 50% return rate from mailed

questionnaires, which also depicted a great deal of data uncollected and unknown, similar to our study. We suggest that future studies should increase the duration to accommodate a larger collection of data, and to conduct a multicenter study to collect more varieties of amputees.

Conclusion

In total, 76.7% of lower extremity amputees were still using their prosthesis in daily life activities. Additionally, 80% rated their satisfaction level as good to very good. The factor most related to satisfaction level was K-level.

Acknowledgement

Conflict of interest

Authors declare no conflict of interest in the study.

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