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Lower Extremity Functional And Mobility Status In Transfemoral Amputees In Malaysia: A Preliminary Study

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Abstract
The feedback from the prosthetic user population is important as it is a part of the process to improve the current technology and ongoing rehabilitation. Thus, the relationship between mobility and life participation in adults with lower extremity conditions needs further investigation. The purpose of this study is to determine the relationship between functional mobility and quality of life among transfemoral amputees. The target group of study (transfemoral amputees) was recruited at three centres in Klang Valley. Two sets of self-report measures such as the Lower Extremity Functional Scale (LEFS) and Prosthetic Limb Users Survey of Mobility (PLUS-M™) were distributed through paper or online form. The independent t-test, one-way analysis of variance (ANOVA), and Pearson correlation were used to test relationships. Data from 30 participants were extracted and included in the study. Average scores for LEFS and PLUS-M™ are 51.53 and 51.84, respectively. The statistical analyses for T-test and ANOVA showed that no significant differences ($p > 0.05$) were found in LEFS Scores and PLUS-M™ T-Scores among groups of transfemoral amputees classified by gender, ethnicity and aetiology. LEFS Score has a moderate positive correlation with the PLUS-M T-Score ($r = 0.600$, $p < 0.001$). Results from the study indicate that both LEFS and PLUS-M™ can be supported as reliable self-report measures to test the functional mobility, quality of life, and daily life activities among transfemoral amputees. LEFS instrument is relevant to assess the functional level and PLUS-M™ helps in evaluating prosthetic mobility.

Keywords: Lower-limb amputation, prosthetics, mobility, rehabilitation, self-report

1. INTRODUCTION

Amputation has been known as one of the most established surgeries performed since ancient occasions such as criminal penalty, therapeutic, and ritualistic (Wilson, 1992). The historical backdrop of lower limb amputation might be followed back to the Neolithic time (Magee, 1998). Back then amputation was the most essential method for the surgeon as it was the speedy technique before the evolution and endorsement of general anaesthesia take place. Limb amputation is considered a safe operation that ending up with a functional stump starting in the early 21st century (Mavroforou et al., 2007). In modern medicine, lower-extremity amputation is mediated as the last hope when it is impossible to save the affected limb and could harm the life of the patient (Paudel, Shrestha, & Banskota, 2005).

In developing countries, the cause of amputation often causes by trauma, unrestrained diabetes mellitus, infections, and tumours (Ubayawansa, Abeysekera, & Kumara, 2016). The statistics showed that diabetes mellitus was the major reason for the amputations done in Malaysia which make up about 75% (Nazri et al., 2019; Yusof, Sulaiman, & Muslim, 2007). The previous study indicated that individuals with lower-limb amputation not simply only lost the anatomical appendage, but also lost the function, sensation, and self-perception after surgery (Breakey, 1997). They may need to ambulate with the help of a prosthesis, a walking aid, or a wheelchair.

As the results of post-amputation altered the functionality, appearance, and structure of the amputees' physique, they need to survive by adapting to the changes physically, psychologically, and socially in the process of rehabilitation (Shankar, Grewal, Agrawal, & Nair, 2020). Physical disability among amputees also contributes to deprivation on financial, social, and psychological impacts including their family and surroundings (Ubayawansa et al., 2016).

The quality of life in individuals with minor amputation was higher in terms of dependency and walking capability even though they have a higher level of discomforts and lack social function compared to individuals with major amputation (Nazri et al., 2019). For major extremity amputation, the population of above-knee amputation is smaller compared to below-knee amputation. Patients with above-knee amputation have higher metabolic costs for ambulation, lower levels of mobility, and a slow rate of

healing compared to people with below-knee amputation.

Several studies on the performance of above-knee amputees have been performed in terms of postural, gait, balance, and so on. Despite the growing popularity of above-knee amputee studies worldwide, it remains a relatively poorly studied concept in developing countries, especially in Malaysia. There is only a piece of limited information on the satisfactory survey of above-knee amputees after post-surgery and the use of the prosthetic device in a long duration. Even though the percentage of amputees use prosthetic leg after post-amputation is about 80%, they tend to re-visit hospitals and re-evaluate their prosthetic devices as sometimes they feel uncomfortable, pain, loose stump and most likely to change to a new prosthesis.

Questionnaire-based survey methods are used in health assessments especially mobility as it can produce exceptional data about people's perceptions, experience, and judgements (Amtmann, Cook, Johnson, & Cella, 2011). The self-report measurement of lower extremity amputees will able to perceive their thoughts and levels of satisfaction on the use of their prosthetic device in daily lives. There are several self-report instruments based on mobility assessments in amputees have been reported in the studies (Condie, Scott, & Treweek, 2006; Heinemann, Connelly, Ehrlich-Jones, & Fatone, 2014). However, they are infrequently used in clinical practice. Some of the reasons might be due to limited knowledge and information in interpreting the scores, uncertainty in the relevancy of items, not enough normative data, and insufficient amount of psychometric test within the focused group (Gaunaurd et al., 2015).

Awareness about the prosthetic mobility performance of the above-knee amputee is crucial for further studies and optimal treatment. Therefore, the purpose of this study was to evaluate the performance of transfemoral amputees with their prosthesis in daily lives by constructing two self-report measurements (LEFS and PLUS-M™). The input from this study may be useful for further researchers to suggest suitable recommendations and improvements in managing patients with an above-knee amputation in Malaysia who undergoing rehabilitation.

2. METHODOLOGY

2.1 Study Design

The study was conducted from December 2019 to April 2020 at two main rehabilitation centres and one local prosthetic company providing services to people with amputation.

2.2 Ethical Review

This study was granted approval from the Medical Research & Ethics Committee's (MREC) through the online application. The web-based service was initiated by the National Institutes of Health (NIH) of the Ministry of Health National called National Medical Research Register (Reference Number: KKM/NIHSEC/P19-2206(11).

2.3 Selection Criteria

The process of selecting subjects used a convenience sampling method and also based on inclusion and exclusion criteria. Convenience sampling was used as there is only a small population of transfemoral patients while the strict requirement in inclusion and exclusion criteria reduce the number of the target population. Any potential patients who came for appointments were approached and asked for their consent before giving the survey form. Some of the patients were contacted through calls and messages for an online survey via a google form.

The selection of participants based on the inclusion criteria according to the questionnaire guideline must be 18 years older, able to read English or Malay language, unilateral amputation with regular use of a prosthesis to stand, transfer or walk. If the patients have no difficulty reading in English or Bahasa, they will be given surveys and asked to read it carefully before answering it. Otherwise, the researcher will read and explain each content of the surveys. This study only focused on above-knee amputation regardless of other types of amputation.

2.4 Participants

The total respondents participated in this survey were 30 transfemoral amputees. The personal contact information of potential candidates was collected beforehand at all respective study sites. The surveys have been distributed among transfemoral amputees who were attending a post-amputation rehabilitation program held by the respective department in three centres within the Klang Valley. The surveys were administered by a paper or in an online form, depending on the respondent's preference. Demographic data such as age, sex, ethnicity, aetiology, side of amputation, type of knee joint used, and location of residence were also recorded.

2.5 Study Instruments

The respondents were given two validated self-administered/interview assisted questionnaires, Lower Extremity Functional Scale (LEFS), and Prosthetic Limb Users Survey of Mobility (PLUS-M™) Version 1.2 (Table 1). The surveys were available in two languages; English and Malay (Yunus, Musa, & Nazri, 2017), which will be selected by the respondents for their preferences. LEFS questionnaire consists of 20 items regarding the ability of an individual to perform everyday tasks. Each item has a maximum score of 4. The total possible score (80) indicates a high functional level. The scale is one page long, can be filled out by most patients in less than 2 minutes, and is scored by tallying the responses for all of the items. This survey is used to evaluate the functional impairment of a patient with lower extremity amputation and the effectiveness of intervention of the patient can be monitored from time to time.

PLUS-M™ questionnaire is a self-report instrument in measuring the mobility of prosthetic users, ranging from household ambulation outdoor recreational activities intentionally and independently. The PLUS-M™ 12-Item Short Form (v1.2) was administered in this study. There are overall three versions for this instrument. The activities focused on two essential outcomes which are movement and postural transitions. The T-Score provided for the 12-item short version ranged from 21.8 to 71.4. A higher PLUS-M™ T-score corresponds to greater mobility. T-scores obtained with the 12-item short-form are highly correlated to those based on all 44 items in the PLUS-M™ item bank ($R^2 = 0.96$).

Table 1. Study instruments.

Instrument	No. of Items	Response Options	Score	Range	Time to Administer
LEFS	20	0 = Extreme difficulty or unable to perform activity 1 = Quite a bit of difficulty 2 = Moderate difficulty	Average score	0 - 80	5 min

		3 = A little bit of difficulty 4 = No difficulty			
PLUS-M™	12	5 = Without any difficulty 4 = With a little difficulty 3 = With some difficulty 2 = With much difficulty 2 = Unable to do	T-score	21.8 – 71.4	2 min

2.6 Statistical Analysis

The analysis was recorded and extracted using SPSS version 26.0. All demographic data were initially screened using the Shapiro–Wilk test and they showed normal distribution. Normal distribution was elaborated using plots and histograms. An independent sample t-test was used to compare the mean scores between male and female groups. Levene's test for equality of variances was tested in to assume the homogeneity of variance. If $p \leq 0.05$, the variances are significantly different and the bottom row of results for t will be interpreted. Meanwhile if $p > 0.05$, the variances are not significantly different and the top row of results in the table will be used for interpretation.

One-way analysis of variance (ANOVA) was assessed to examine whether there is a significant difference existed in LEFS and PLUS-M™ scores between ethnicity and aetiology or otherwise. All analyses determine that the significant value was accepted at $p \leq 0.05$. For any significant difference detected, further analysis by using post hoc analysis will be performed using the Tukey's Honestly Significant Difference test and Scheffe's method to determine where the differences occurred.

Pearson's product-moment correlation (Pearson's r) obtained from the multiple regression analysis was used to indicate the relationships between LEFS and PLUS-M™. The r classification can be categorized into for groups. Value of r = 0:0 to 0.2 describes very weak relationship, r = 0:20 to 0.4 for weak relationship, r = 0:4 to 0.7 as moderate relationship, r = 0:7 to 0.9 as strong relationship, and r = 0:9 to 1.0 indicates very strong relationship. Pearson correlation coefficients and 95% one-sided lower limit confidence intervals were calculated to examine the relationship between the LEFS and PLUS-M™ scores.

3. RESULTS

3.1 Demographics of Participants

A total of 30 transfemoral amputees completed the survey given either through printed papers at study sites (N = 20) or online form (N = 10). Table 2 shows the demographics of participants such as gender, race, cause of amputation, type of knee joints used, side of amputation, and range of age participated in the study. Male subjects made up a large number of participants with 80% of the study and the rest 20% were female. Most populations came from the Malay community with 53.3%, followed by Indians (26.7%) and Chinese (20.0%). Majority of amputation caused by traumatic cases with a percentage of 73.3%, while the remaining 26.7% were due to vascular causes such as infection and diabetes. More than half of the amputees use polycentric prosthetic knee joint (56.7%), while the second highest is the pneumatic prosthetic knee joint with a percentage of 23.3%, followed by hydraulic and single-axis prosthetic knee joints which are 13.3% and 6.7% respectively. About 66.7% of the participants have amputation on the right side. The range of age was between 21 to 62 years old with a mean ± SD (38.40 ± 14.45).

Table 2. Demographics of participants (N = 30).

Characteristics	Frequency	Percentage (%)
Sex		
Male	24	80
Female	6	20
Ethnicity		
Malay	16	53.3
Chinese	6	20.0
Indian	8	26.7
Aetiology		
Traumatic	22	73.3
Diabetes	3	10.0
Infection	5	16.7
Type of Knee Joint		
Single-axis	2	6.7
Polycentric	17	56.7
Pneumatic	7	23.3
Hydraulic	4	13.3
Side of Amputation		
Right	20	66.7
Left	10	33.3

Characteristics	Range	Mean	SD
Age (years old)	21 – 62	38.40	14.45

*Note. SD = Standard Deviation

3.2 Scores Interpretation

Descriptive statistics for the patients by the measure are presented in Table 3. None of the patients received the minimum or maximum scores for the LEFS and PLUS-M™ at any of the assessments. The results show that the comparison values of mean, percentiles, standard deviation, and range between LEFS Score and PLUS-M™ T-Score are almost identical to one another except for maximum values. Minimum and maximum LEFS Score obtained were 22 and 71 out of 80 respectively, while PLUS-M™ T-score has a minimum score of 21.8 and the highest T-score recorded were 62.50 out of 71.4. The mean for LEFS Score is slightly lower (51.53) than the PLUS-M™ T-Score (51.84). PLUS-M™ T-Score has a higher standard deviation (11.84) compared to the LEFS Score (8.12). The value of median, upper and lower bounds shown in Table 4 are almost identical to one another. The slight difference in the interquartile range is due to the different maximum scores (Table 4).

Table 3. LEFS score and PLUS-M™ T-score of transfemoral amputees (N = 30)

	LEFS Score	PLUS-M™ T-Score
Mean	51.53	51.84
25th Percentile	42.00	46.40
50th Percentile	54.50	53.60
75th Percentile	58.40	58.40
Standard Deviation (SD)	11.84	8.12
Range (min – max)	49 (22 – 71)	40.70 (21.80 – 62.50)

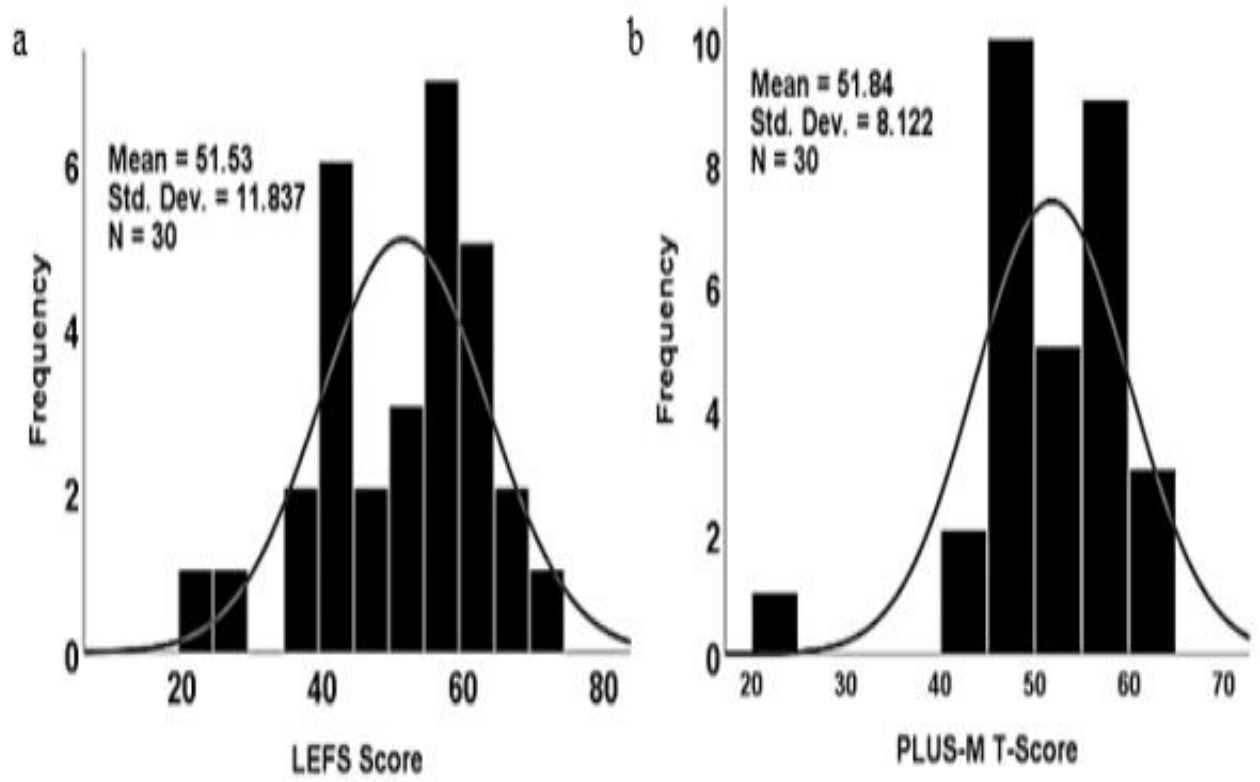

Figure 1. Histogram of (a) LEFS score and (b) PLUS-M™ T-score for all participants.

Table 4. Interquartile range for LEFS score and PLUS-M™ T-score.

	LEFS	PLUS-M™
Mean ± SE	51.53 ± 2.16	51.84 ± 1.48
Lower Bound	47.11	48.80
Upper Bound	55.95	54.87
Median	54.50	53.60
SD	11.84	8.12
Minimum	22.00	21.80
Maximum	71.00	62.50
Interquartile Range	18.50	12.00

*Note. SE = Standard Error

3.3 Average of LEFS Score and PLUS-M™ T-Score

The comparison of average for both scores between several factors such as gender, ethnicity, aetiology and type of knee joints used among transfemoral amputees can be observed as shown in Fig. 3(a), (b), (c), and (d). Male groups gained a higher average for LEFS Score and PLUS-M™ T-Score (52.50, 51.99) compared to female groups (47.67, 51.22). Malays have the highest average for both scores (54.06, 53.79) while second higher scores for LEFS and PLUS-M™ were opposite to each other where Chinese held the second place (51.17) followed by Indians (46.75) for LEFS Score, and Indians have a higher average (51.49) than Chinese (47.10) for PLUS-M™. For aetiology category, traumatic patients obtained the highest scores (53.73, 53.08), next is infection (48.80, 51.10) and the lowest is due to diabetes (40.00, 43.93). All respondents used passive prosthetic knee mechanism and the results show that transfemoral amputees with pneumatic knee joints have the highest average for both scores (59.00, 54.66) followed by hydraulic (50.50, 53.40), polycentric (49.71, 51.54) and the least scores counted by participants with single-axis knee joints (43.00, 41.40).

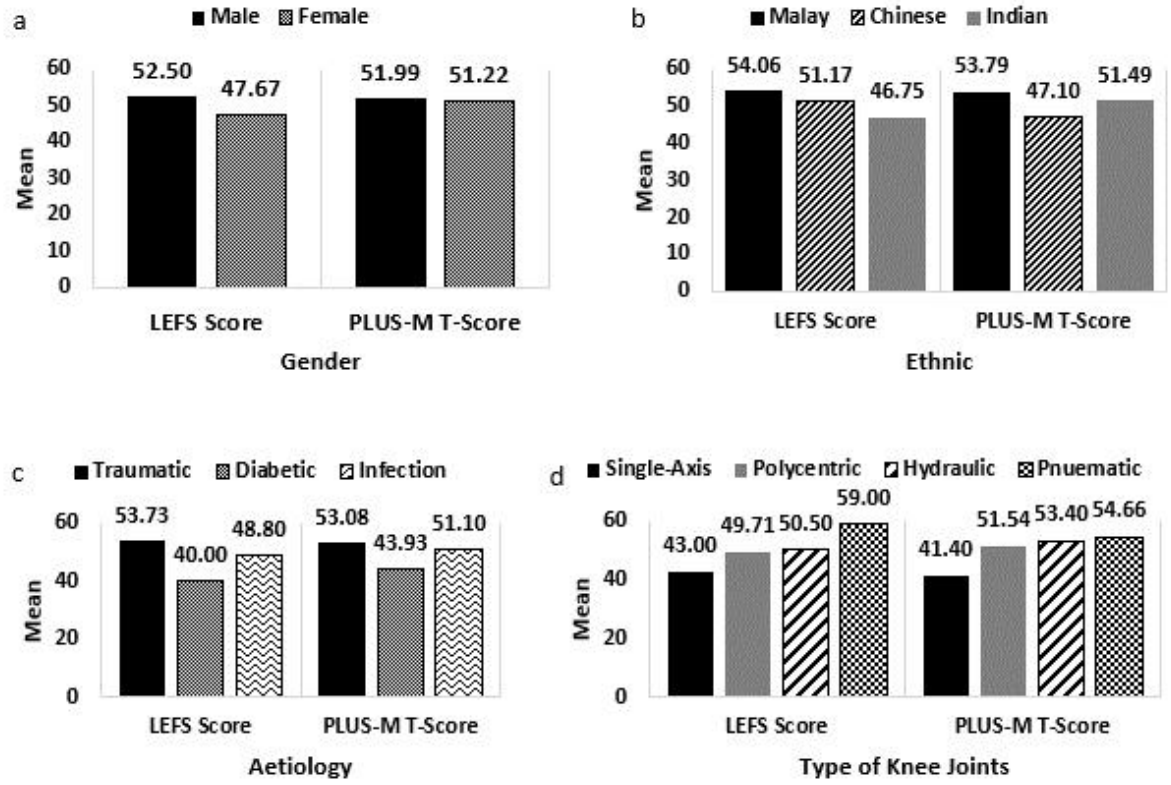

Figure 2. Comparison between the average of LEFS score and PLUS-M™ T-score with demographics of participants such as (a) gender, (b) ethnicity, (c) aetiology, and (d) type of knee joints.

3.4 statistical Analysis

An independent-sample t-test was conducted to compare the scores between male and female groups (Table 5). There was no significant difference in the reported scores for gender, (LEFS: $t_{28} = 0.89$, $p = 0.380$; PLUS-M™: $t_{28} = 0.21$, $p = 0.380$) despite men ($\bar{X}$ = 52.50, 51.99) attaining higher scores than women ($\bar{X}$ = 47.67, 51.22). One-way ANOVA analyses were performed for factors with more than two groups; ethnicity and aetiology. There were no statistically significant differences between ethnicity group means as determined by one-way ANOVA for LEFS ($F_{2,27} = 1.023$, $p = 0.373$) and PLUS-M™ ($F_{2,27} = 1.545$, $p = 0.232$). The similar no significant results were obtained between aetiology category for both scores (LEFS: $F_{2,27} = 2.079$, $p = 0.145$; PLUS-M™: $F_{2,27} = 1.792$, $p = 0.186$). Pearson correlation measured the degree of the linear relationship between the LEFS and PLUS-M™ scores. The obtained value for r is 0.600 which indicates that both instruments have a moderate positive relationship in this study as shown in Figure 4.

Table 5. Independent T-Test and one-way ANOVA statistics for LEFS score and PLUS-M™ T-score

Score	Test	Gender		Ethnic			Aetiology		
		Male	Female	Malay	Chinese	Indian	Traumatic	Diabetic	Infection
LEFS	$\bar{X}$	52.50	47.67	54.06	51.17	46.75	53.73	40.00	48.80
	p	0.380		0.373			0.145		
PLUS-M™	$\bar{X}$	51.99	51.22	53.79	47.10	51.49	53.08	43.93	51.10
	p	0.839		0.232			0.186		

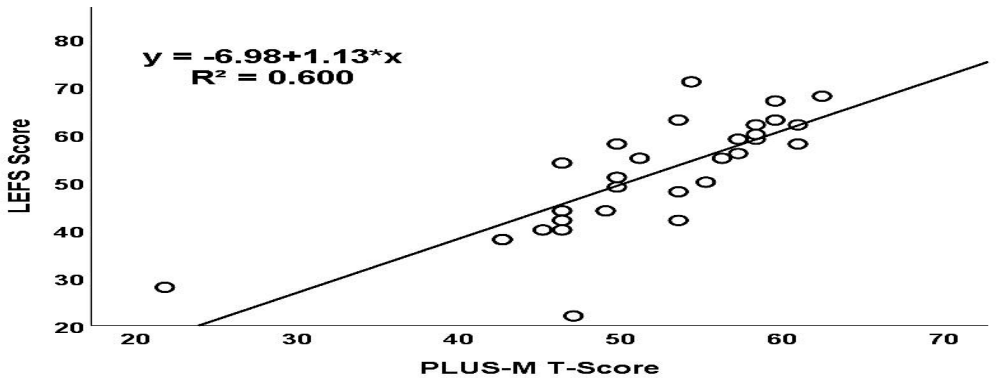

Figure 3. Pearson correlation between PLUS-M™ T-Score and LEFS Score among participants ($N = 30$).

4. DISCUSSIONS

The objective of this study was to evaluate the performance

of the prosthetic devices in transfemoral amputees during post-amputation and how it affects their everyday routine. Patient-rated outcome measures (PROMs) are often used in healthcare studies (Hafner, Morgan, Abrahamson, & Amtmann, 2016). The initial LEFS assessment was paired with SF-36 scores to determine the reliability and validity via statistical analysis (Binkley, Stratford, Lott, Riddle, & Network, 1999). This study combined two self-report instruments, LEFS and PLUS-M™ 12-item where the statistical analyses were performed to study the relationship between these two scores. LEFS instrument measured the ability of an individual with lower extremity musculoskeletal condition to perform everyday tasks. Meanwhile, the PLUS-M™ is essentially used where the mobility is the primary outcome and this study focused on prosthetic user of passive mechanism. No comprehensive studies have been found that using both instruments together to assess transfemoral amputees in this country.

The LEFS self-report instrument can be used to evaluate patients' outcomes, initial activity, continuing development to set functional targets. The score calculation for this questionnaire is more direct compared to PLUS-M™. The final score is obtained by summing the columns on the scale. The scale of item survey scores has a standardized average (SD) of 50 (10). The previous study showed that the highest and lowest means recorded are 56 and 34, respectively (Binkley et al., 1999). The average score among the total of 30 participants in this study is 51.53 (11.84) and it is slightly above than the standardized average. Based on Table 5, the highest score achieved in this study is 71 out of 80 points where the lowest score recorded is 22 points. The highest scores indicate a high functional level of patients (Binkley et al., 1999).

A higher level of mobility can be represented by achieving a higher PLUS-M™ T-score. In the manual, the highest T-score achieved when a respondent marked "without any difficulty" while respondent with the lowest score picked "unable to do" for all items. The previous PLUS-M™ test recorded the lowest and highest means of 25.2 and 71.4 respectively, where the average (SD) was 51.8 (9.3) (Hafner, Morgan, Askew, & Salem, 2016). Another study recorded an average (SD) of 50.3 (8.0) and the score range was between 27.2 to 71.4 (Hafner et al., 2017). The highest score of an individual achieved in this study was 62.5 (3.1). By referring to the T-score conversion table, it indicated that high mobility was reported by that particular respondent compared to 89.5% of the development sample. Meanwhile, the lowest T-score achievement of an individual is 21.8 (4.4). This score recorded as the minimum score achieved in the table score and it indicated that the respondent was included among 0.2% of the development sample. The average T-score (51.84) showed that this study group reported higher mobility than 57% of the development sample (Lee; Wurdeman, Stevens, & Campbell, 2018).

Previous studies stated that the lower extremity function decreases as age is increasing. Even though women had a significantly lower score than men, the difference was insignificant and it was not clinically relevant to make a comparison (Dingemans et al., 2017). The average of the two scores was almost identical for both men and women categories. A slightly low scores can be observed in women groups for LEFS Score. The small difference in mean scores between men and women might happen because of the unequal sample size of that category. Malays have the highest score for both surveys, while Chinese and Indian communities score second-highest for LEFS and PLUS-M™ respectively. The highest scores obtained by the Malays might be due to a large number of participants compared to other ethnics. The number of Malay respondents was larger than the sum of Chinese and Indian respondents.

Respondents with traumatic amputation have higher scores followed by infection cases. Individuals with diabetes diseases scored the lowest for both questionnaires. In comparison between the prosthetic knee joints group, participants with pneumatic knee joints performed better than other groups. Hydraulic and polycentric users almost have the same means while single-axis users achieved the lowest scores. The small differences of means in hydraulic group might happen due to a small sample collected compared to the polycentric group in this study. Concerning the previous study of validity, a greater functional level produced higher PLUS-M™ T-Scores. It can be said that the scores increased significantly as the Medicare Functional Classification Level (MFCL) is higher (Hafner et al., 2017).

The independent t-test between scores has no significant effects on gender. Similarly, for ANOVA analysis, it showed that all probabilities are higher than 0.05 between scores and other factors such as ethnicity and aetiology. As the statistical results showed no significant difference between all factors, no further post-hoc analysis was included in this study. The same status for LEFS and PLUS-M™ showed that the transfemoral amputees experience the same functional state regardless of gender, ethnicity, and aetiology in this study. The correlations for the previous study between PLUS-M™ and other self-report measures such as AMP, PEQ-MS, ABC, and PROMIS-PF have been reported as 0.26, 0.59, 0.68, and 0.62, respectively (Hafner et al., 2017). The moderate positive correlation observed between both instruments in this study proved that LEFS and PLUS-M™ instruments are relevant to assess the quality of life and mobility functional for transfemoral amputees.

The self-report instruments assessed directly based on their thoughts, behaviours, and feelings regarding the use of prostheses to carry out their daily lives. Based on the data collection among transfemoral amputees, it represented the subjects' perceived performance regarding functional prosthetic devices during post-amputation and rehabilitation phase. The results from this study may be used as a piece of supplementary evidence and another test of biomechanical assessment that will be conducted to test the reliability. This outcome measurement may help other biomechanical researchers in developing advanced analytics to improve the quality of life among lower-limb amputees in the future.

5. CONCLUSIONS

Ongoing prosthetic rehabilitation for transfemoral amputees after post-amputation is a crucial phase for them to regain their confidence in terms of psychological and physical effects. The prosthetic rehabilitation should not only focus on mobility improvement, it is important to consider the general satisfaction and quality of life too. As the results for both self-reports produced a moderate positive correlation, this study supports that the use of LEFS and PLUS-M™ as self-report instruments are relevant in evaluating prosthetic mobility, quality of life, and activities in daily living as well as used in clinical care. The outcomes of this study support the relevance of using the LEFS instrument in measuring the functional level and PLUS-M™ is essential for a prosthetic mobility assessment. The current study considered two items that related to assessing perceived balance confidence during dynamic activities such as walking inside outside the house, negotiating ramps, doing the chores including light and heavy activities. Further assessments such as test-retest reliability, construct validity and predictive validity of other instruments are recommended. The results may be used as supplementary evidence for the next biomechanical assessments in terms of temporal-spatial, kinetics and kinematics.

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