Preliminary Validation of the LEGS Functional Parameters Questionnaire

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Introduction

Simple, robust, reliable and valid outcomes measures which can be utilized in less resourced settings are badly needed. Data from appropriate outcomes measures can shed light on the functionality of prosthetic devices for all of the World Health Organization's International Classification of Function categories[1] confirming that devices meet users needs effectively, informing design, and ensuring that limited funds are spent efficiently[2,3]. As alternative devices and access to rehabilitation become increasingly available in less resourced settings, objective outcomes can inform prescription and rehabilitation protocols[2,3]. Questionnaires are commonly used in the developed world to provide quantitative feedback from prosthetic device users[4]. However, existing validated questionnaires often have questions which are culturally inappropriate in less resourced settings (such as escalator use in the OPUS survey[5]) or personal care questions specific to western conditions[5]. Many are also too lengthy, and difficult to administer in less resourced settings[4]. It is apparent that a brief questionnaire which is easy to administer and valid in less resourced settings would be inherently valuable. Therefore, we have embarked on the development and evaluation of the *LEGS Functional Parameters Questionnaire* (LFPQ) as a means of assessing the functionality of lower limb prosthetics and orthotics in less resourced settings

METHODS

A preliminary version of the LEGS Functional Parameters Questionnaire (pLFPQ) with 20 questions utilizing a visual analogue scale was developed in 2008 based on modified questions from the Prosthetic Evaluation Questionnaire[6] (PEQ) and additional questions regarding the functionality in phases of gait.

The pLFPQ was tested in Kenya and Bangladesh with preliminary results showing sufficient validity and sensitivity to differentiate meaningfully between two knee conditions[7]. An expanded version of the pLFPQ called the eLFPQ with 34 questions also was created to test for parallel forms validity and to determine the most functional wording for each question. This was then administered to two subject groups as part of a suite of outcomes consisting of a six minute Timed Walk Test[4] (TWT), Physiological Cost Index[4] (PCI), quantitative gait data (GAITRite™) (reference), the timed "Up-and-Go" test[8], and several other short timed tests.

Eighteen unilateral transfemoral amputees with few co-morbidities (29 +/- 6.30 yrs, 14 M, 4 F) in Kenya and Bangladesh participated. The study used the LEGS M1 polycentric knee which has been designed for use in low-income countries[9,10,11]. The knee was used in both both a free swinging and locked configuration.

In another comparison using the same outcomes measures for two knee conditions forty-six college students (19 +/- 1.33 yrs, 27 M, 19 F) participated wearing a Bledsoe Extender brace set at 0 and 10 degrees flexion.

Data from the eLFPQ was standardized using a z-distribution with GAITRite spatial and TWT data standardized to leg length. GAITRite temporal data was standardized by percent of stride time. For the larger study group, principle components analysis was performed to inform correlation analysis. eLFPQ data was then correlated with the other outcomes measures to assess construct validity while correlation significance was determined using a standard chart of sample-size-dependant critical values of the Pearson Correlation

Coefficient[12]. Cronbach's alpha analysis was utilized to test for internal consistency for each group. Reverse-scaled repeated questions in the eLFPQ were also tested for parallel forms validity. Paired T-tests looking for significant differences between knee conditions in each group were utilized to test for sensitivity and to confirm construct validity.

RESULTS

LEGS M1 knee vs. a locked knee condition

The eLFPQ was able to differentiate in a meaningful way between the LEGS M1 knee and a locked knee condition. Due to space limitations, Table 1 shows the key results. For the four eLFPQ questions below, the LEGS M1 knee was perceived in a more positive light; it also had a longer prosthetic step length and narrower base of support.

Table 1: Selected paired T-tests results between prosthetic knee conditions

Gait Factor	**P-Value**
Prosthetic Step Length	0.003
Heel-to-Heel Base of Support	0.024
eLFPQ	**P-Value**
Question 17 - Energy Efficiency	0.004
Question 39 - Ease in Swing Through	0.011
Question 42 Walking Stability	0.033
Question 44 Normality of Gait	0.047

Multiple correlations between eLFPQ results and other outcomes measures occurred; many of these were as logically expected; key results are listed in Table 2.

Table 2: Correlations Between Prosthetic Gait and eLFPQ Responses

Correlating Factors	**P Value**	**R Value**
Q34 Tight Spaces --- NR B Stride Width	0.020	-0.385
Q34 Tight Spaces --- NR P Stride Width	0.019	-0.389
Q17 Energy to Walk --- B Stride Time	0.049	-0.330
Q17 Energy to Walk --- P Stride Time	0.047	-0.333
Q16 Exhaustion While Walking --- PCI	0.031	0.360
Q40 Balance Walking --- PCI	0.005	0.458
Abbreviations: Q7 = Question 7, etc. B = Biological, P = Prosthetic, NR = Normalized		

Knee brace set at 0°and 10°flexion

The eLFPQ was able to differentiate in a meaningful way between similar knee brace conditions. For most factors, the brace set at 10° flexion was perceived in a more positive light and other outcomes measures echoed this pattern; selected T-test results are in Table 3.

Table 3: Selected paired T-tests results between knee brace conditions

Gait Factor	**P-Value**
Step Length Symmetry	0.008
Step Width Symmetry	0.012
Step Time Symmetry	0.020
Swing Time Symmetry	0.041
eLFPQ Answer	**P-Value**
Question 9 - Walking Effort	0.001
Question13 - Difficulty in Swing Through	0.000
Question 42 - Walking Stability	0.001
Question 44 - Normality of Gait	0.017

Like the prosthetic knee study, multiple significant correlations were seen in the knee brace study (see Table 4). Because this study had a larger sample size and higher statistical power, it was better able to resolve relationships between the eLFPQ and other measures.

Table 4: Correlation Between Brace Gait and eLFPQ Responses

Correlating Factors	**P Value**	**R Value**
Q34 Tight Spaces --- B HH Base of Support	0.021	-0.233
Q34 Tight Spaces --- P HH Base of Support	0.046	-0.202
Q22 Likelihood of Falling --- SI Step Length	0.001	0.338
Q22 Likelihood of Falling --- SI Step Width	0.013	0.251
Q22 Likelihood of Falling --- SI Swing Time	0.004	0.228
Q42 Stability Walking --- TWT	0.006	0.278
Q44 Normality of Gait --- TWT	0.020	0.235
Q40 Balance Walking --- PCI	0.002	0.309
Q44 Normality of Gait --- PCI	0.018	0.238
Q41 Stability Standing --- "Up-and-Go"	0.026	0.225
Abbreviations: Q7 = Question 7, etc. B = Biological, P = Prosthetic, HH = Heel-to-Heel, SI = Symmetry Index		

Additionally, cronbach's alpha scores revealed a high internal consistency in eLFPQ scores in both studies (see Table 5).

Table 5: Cronbach's Alpha scores for internal consistency

Test Group	Knee Condition	Alpha
Amputees (n=18)	LEGS M1	0.891
Amputees (n=18)	locked	0.944
Students (n=46)	brace 10 ° flexion	0.948
Students (n=46)	brace 0° flexion	0.943
*Cronbach's Alpha scores from 0.70-0.90 are considered moderate to excellent		

The parallel forms reliability intraclass correlation coefficient (ICC) score for combined data from both group's eLFPQ responses was moderate (see Table 6).

Table 6: Intraclass Correlation Coefficient: All Groups All eLFPQ Responses

Test Group	Knee Condition	ICC
Amputee/Student	All Conditions	0.63

DISCUSSION

T-test results indicate the eLFPQ has the sensitivity to differentiate between polycentric and locked knee conditions and between similar knee brace conditions.

Construct validity is demonstrated by T-test results and by correlations. T-tests indicating significant differences between the prosthetic knee conditions meet logical expectations and are substantiated by GAITRite™ data which picked up differences in gait between the two sets of knee conditions in a way that quantitatively mirrors LFPQ results. This was also the case with the data from 0° and 10° brace conditions; subjectively more positive responses on the LFPQ for the brace set at 10° flexion mirrored positive PCI and GAITRite™ results which indicated the 10° brace allowed more symmetrical and energy efficient gait

Correlations indicate logical expectations in both studies. For example, in the prosthetic study two of many such correlations are between perceived functionality in tight spaces and decreased heel-to-heel base-of-support. In the knee brace study significant correlations were observed as expected between eLFPQ responses and a variety of quantitative test results, including TWT distances, Physical Cost Indexes, and multiple gait parameters.

For the prosthetic knee study, responses on the eLFPQ did not seem to be echoed in TWT results. Many of the amputees in our study had spent long periods of time (>2 years) walking with a locked knee before being introduced to the polycentric knee used in this study. While all amputees wore the polycentric knee for at least 1 year before the study, proficient walking patterns with a locked knee may have persisted. This could explain the lack of differences observed in TWT results; though it cost them energy, it seems that they had the skill and endurance to walk quickly for six minutes with a locked knee condition.

Internal consistency scores observed in both amputee and student trials indicate that the eLFPQ is not only differentiating between knee conditions, it is doing so reliably across its range of questions.

Further testing is underway with a final 19 question LFPQ questionnaire. Additional testing with other lower limb conditions, specifically prosthetic foot and ankle brace conditions is also underway. All populations tested to date have been relatively young and physically fit. Testing is needed with older and less fit populations and with children.

CONCLUSIONS

The LFPQ along with the other measures provides a valuable broad look at knee function. Preliminary results indicate that the LFPQ displays the validity and sensitivity to differentiate between various knee conditions in a meaningful way. Results were substantiated by quantitative TWT, PCI, GAITRite, and "Up-and-Go" results, indicating construct validity. Strong internal consistency was displayed in eLFPQ responses in both test groups.

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