PRELIMINARY CONSTRUCT VALIDATION OF THE LOWER LIMB FUNCTION QUESTIONNAIRE

Luke Funk, Danielle Thiessen, Virginia Wright, Jan Andrysek, Karen Rispin
LeTourneau University Wheels Project

INTRODUCTION

There is a need for outcomes studies on lower limb prostheses and orthoses designed for use in low-resource settings [1, 2]. Questionnaires previously available are difficult to administer in low resource settings, include questions not suitable for most participants in those settings, or produce data not appropriate for sensitive parametric statistical analysis [3-5]. In response, development of the questionnaire now called the Lower Limb Function Questionnaire (LLFQ) was initiated by our team and then refined through several studies [6]. Initial work with the LLFQ was undertaken primarily with young adult participants using above-knee prostheses [7]. Usage has since been extended to include individuals who use orthoses to meet an area of assessment need [5]. The LLFQ consists of 20 items covering various aspects of lower limb functionality, including walking up and down stairs, ramps, sitting and standing, running, walking, balance, pain, discomfort, appearance, comfort, awkwardness, and sound. The last question asks participants to rate their satisfaction with the overall function of their lower limbs. Each item is scored using a visual analogue scale (VAS) format with emoticons at the left and right ends of a 100 mm line. Marks at the left end of the VAS line indicate a lower rating. Clinically, we have found that most adults and school children have a strong understanding of school grades as a rating scale, therefore school grades are also placed as anchors under the VAS line to enable more intuitive response. Validation of this format is also underway.

Test-retest reliability of the LLFQ when used with teens and young adults (n=40) with lower limb orthoses, prostheses or gait abnormalities was found to be excellent (ICCs > 0.80) for the word anchored and grade based VAS scales (reported in a separate paper that is under review). As a first step in construct validation of the LLFQ, we hypothesized that higher LLFQ scores would correlate with better gait characteristics and lower energy cost.

METHODS

Participants

Participants were recruited from students with gait abnormalities at a boarding school for children with disabilities in a low-resource setting. Many participants used lower limb orthoses or prostheses (Age=16.18 ± 2.37 years, 30M, 31F). See Table 1 for categories of participant disabilities and Table 2 for categories of assistive devices. The study protocol was approved by the institutional review board of LeTourneau University as well as the ethics committee of our partner organization at the study site. All participants/guardians completed consent/assent forms and participants were free to withdraw or opt out at any point.

Table 1: Participant Disabilities

Disability	*Participants (n=61)*
CP[1]	20
TR[2]	10
CG[3]	10
SB[4]	9
CF[5]	3
Other or Unknown	9

[1]Cerebral Palsy [2]Trauma and Infections [3]Congenital Malformation [4]Spina Bifida [5]Clubfoot Corrected

Table 2: Participant Assistive Devices

Assistive Device	*Participants*
RS[1]	16
KAFO[2]	8
AFO[3]	7
AK[4]	6
BK[5]	2
Other Gait Abnormality[6]	22

[1]Raised Shoe [2]Knee Ankle Foot Orthoses [3]Ankle Foot Orthoses [4]Above-Knee Prostheses [5]Below-Knee Prostheses [6]Mostly participants with CP

English was the primary language spoken at the school; therefore the LLFQ and other test instructions were given in English. LLFQ was administered to all participants at the same time. Detailed instructions were given verbally at the beginning of the session. The questionnaire was read question by question and enough time was given for all students to complete each question before moving on to the next. The numerical rating and comments were recorded for each LLFQ question.

Walk Tests

Walk tests were completed by a group of 45 of the LLFQ participants. This included the six minute Timed

Walk Test (TWT) [8, 9]. Participants also completed a six minute timed test at a self-selected pace on an obstacle course track which included walking up and down 5 stair steps, up and down a low-incline ramp, and weaving between 4 chairs placed 0.5 meters apart. Participants sat between tests and rode in a wheelchair between testing locations to ensure they were rested before the start of each test. In both tests, distance traveled in six minutes was measured using a survey wheel. The FitMate Pro portable metabolic unit from COSMED was used to obtain participant oxygen consumption data for the last four minutes of each timed test [10]. Oxygen consumption was standardized by subject weight. Three students with advanced gait disabilities opted out of the stairs portion of the obstacle course.

Gait Evaluation and Timed Up-and-Go Tests

Gait evaluation and Timed Up-and-Go (TUG) tests were completed by an overlapping but not identical group of 42 LLFQ participants. Time restrictions precluded all participants from completing all tests in a single session. Gait analysis was achieved with GAITRite, a 14-foot long instrumented gait analysis mat [11]. Participants walked at a self-selected pace 15 times across the GAITRite mat, and chairs were placed at each end of the mat to enable subjects to rest at any time. GAITRite was used to measure participants' mean stride length, mean step length and mean cadence across the 15 trials. The TUG test was used as an additional validated measure of functional mobility [12].

Data analysis

Data Analysis was completed using MedCalc data analysis program to perform the correlation analyses with an adjusted P = 0.01 to handle analysis of multiple correlated outcomes. The LLFQ total score was summarized as a percentage score.

RESULTS

For the first set of measures (n=42 participants), the LLFQ mean score was 64.9 (SD=14.3, range = 36.4 to 97.6) with a normal distribution. Correlations with the LLFQ total score were as follows: step length (r = 0.45, P=0.002), stride length (r = 0.44, P=0.003), cadence (r = 0.20, P=0.17), and TUG (r =-0.33, P =0.03). For the second set of measures (n = 42 participants), the LLFQ mean score was 63.3 (SD=14.2, range = 27.0 to 95.0) with a normal distribution. Correlations with the LLFQ total score were as follows: distance traveled on the TWT (r = 0.24, P = 0.11), distance travelled on the obstacle course track (r = 0.58, P = 0.001), mlO_2/min for the TWT distance (r = -0.15, P = 0.32), and mlO_2/min for the obstacle course distance (r = -0.09, P =0.89).

DISCUSSION

The distance traveled on the obstacle course walk was significant along with stride and step length results. We did not expect more than a moderate r value since the physiological and gait tests do not measure all aspects covered in the questionnaire.

Gait characteristics in this study, including stride and step length, are broadly accepted to be indicative of functional gait. Longer strides and steps are known to correlate with functional walking ability [13, 14]. In addition, longer Timed Up-and-Go completion times are understood to indicate a lower level of walking ability [15].

The obstacle course included more aspects of the questionnaire than any other test and exhibited stronger correlation as expected. LLFQ responses correlated with distance travelled on the obstacle course; however, the correlations with oxygen consumption were not significant. This may be due to the participants' maintenance of consistent energy expenditure rather than of consistent speed. Instead of tolerating a higher energy cost, participants who experienced greater difficulty walking during the walking tests seemed to choose to complete the tests at a slower pace than those who found little difficulty.

Study limitations

Administering the questionnaire in a large group setting may have reduced the ability to concentrate for some participants and did not allow for much personal interaction to clarify the meaning of questions. English was not the first language of the participants, however it was the language of schooling.

CONCLUSION

The obstacle course included many aspects covered in the LLFQ and consequently correlated well with participant responses. Distance on the obstacle course, and step and stride length were all moderately associated with LLFQ scores, providing preliminary support for the LLFQ's construct validity.

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