A Study of Performance-Based Outcome Measures Used in the Prosthetic Field: Establishing Normative Values for Transtibial Amputees

Amelia Weingart

Advisor: Dr. Blain Harrison

University of Florida

Department of Applied Physiology & Kinesiology

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Abstract

Within the prosthetic field, many outcome measures are used to assess functional ability of amputees. This study examines the Amputee Mobility Predictor test (AMP), the Ten Meter Walk test (10mWT) and the Timed up and Go test (TUG) to assess correlation between them and attempt to establish normative data for this patient population. The data was obtained from an orthotics and prosthetic clinic located in Gainesville, Florida. Overall, the expected trends were seen: amputees that have higher functional abilities deemed by their k-level and AMP test results have faster walking speeds and shorter TUG times. Thus, this study supports the findings of previous research in validating the use of these outcome measures. Normative data was able to be established but was not proven to be reliable or conclusive because the standard deviations fore each group were too large. Further research is warranted to establish valid normative values that can be used clinically since they may have many benefits for both patients and clinicians.

Introduction

As technology advances, the number of people who are able to live with missing limbs and remain functionally independent increases.[1] Thousands of people, among all ages, with unilateral or bilateral lower limb amputation live today.[1] The leading causes for extremity loss are vascular disease, trauma and cancer.[1] Fortunately, prosthetic intervention allows these individuals to preserve their functional independence. Currently, amputees have options for various prosthetic components based on their ambulatory status and gait.[2] Some components are suited for someone who might have been an athlete prior to amputation and desires to continue living at that same activity level. Other components don't allow for as much flexibility but provide a steady and dependable prosthetic limb. These would meet the needs of an older or relatively sedentary individual who might not need as much versatility with their prosthesis.

Thus, it is critical that an amputee receive a prosthesis with components that meet the demands of his or her lifestyle.

Components deemed appropriate are based off of an amputee's functional ability which can be assessed by using the Amputee Mobility Predictor (AMP) test.[3] It aims to predict the functional ability of an individual with a prosthesis regardless of what stage of prosthetic intervention they are currently in.[3] It also categorizes amputees by their functional abilities.[3] There are 5 categories (K0, K1, K2, K3, K4) that are each defined by differing levels of functional ability.[3]

These categories are used by Medicare to determine which prosthetic components are most appropriate for an individual. The reliability of the AMP test and designation of MCFL is extremely important since it provides information to Medicare and other insurance companies of what to expect from a new amputee. It can determine what prosthetic components will be covered by insurance so proper classification is imperative for an amputee to receive a prosthesis that suits their needs.

The AMP test is one of many functional outcome measures used to track progress and functional mobility of a person who uses a prosthesis. Other common functional outcome measures used include the ten meter walk test (10mWT) and the timed up and go test (TUG). Both the 10mWT and the TUG test have been used to assess mobility and balance in other patient populations in addition to amputees.[4] The validity and reliability of all three of these functional measures have been tested and retested on various patient populations and are shown to be useful assessments.[5] Functional outcome measures have the potential to be extremely useful in a clinical setting. However, the usage of outcome measures in this field is relatively new and systematic guidelines or protocols have not yet been established to best utilize these

tools. Many new outcome measures are also being designed to assess functional ability and the psychosocial effects of using a prosthesis and being an amputee. Thus, there is an imminent need to educate clinicians on how to best use them in practice.

Though there is normative data available for the 10mWT and the TUG test for healthy individuals and even for other patient groups, normative data for these tests have yet to be established for lower limb amputees.[6,7] This study aims to examine the test results of the 10mWT and the TUG test for transtibial amputees to create normative values specific to the amputee population based on k-level and gender. We also desire to examine the correlation between all three outcome measures and confirm their usage in determining an amputee's mobility status.

Review of Literature

The number of people living with lower limb amputations in the United States has grown and is expected to continue growing.[1] One study suggests that the prevalence of limb loss will more than double by the year 2050.[1] This is mostly based on an aging population and an estimated increase in the prevalence of diabetes. These statistics lend themselves to the need for proper programs available for these individuals to receive a prosthetic limb. Currently, amputees have options in regards to prosthetic design and included components based on their functional abilities, gait pattern and personal goals.[2] For both transtibial and transfemoral amputees, there are various foot choices, suspension mechanisms, and other component options that meet the activity level of each patient. Transfemoral amputees also have choices of knees for their prosthesis. Manufacturers of these components provide clinicians with suggested k-levels for each component. It is important to designate the proper prosthetic components that are most appropriate for each patient, so there must be a system to categorize functional ability of the patient and of the components.

Currently, there are many performance-based and self-reported outcome measures available that assess functional ability and psychological factors that may affect the progress of a prosthetic patient. This study focuses on the following measures: the AMP test, the 10mWT, and the TUG test. The AMP test is specifically used for amputees only while the 10mWT and the TUG test are used for other patient populations in addition to amputees. All three measures assess different aspects of functional ability and must be administered by another trained individual.

The AMP test includes two versions, one using a prosthesis (AMPPro) and one without using a prosthesis (AMPnoPro). This test aims to classify prosthetic patients into categories of functional status called K-levels or Medicare functional classification levels (MCFL).[3] The AMP assessment includes a battery of 27 tests that evaluate balance, gait, and ability to transfer among other abilities necessary for Activities of Daily Living (ADLs).[3] It gives a score ranging from 0 to 43 for the AMPnoPRO test and 0 to 47 for the AMPPro test.[3] These scores then correspond to the five K-level groups. Table 1 shows the scores ranges for each k-level for AMPPro and AMPnoPRO. A higher AMP score correlates with greater functional ability and a higher K-level designation.

According to the US Health Care Financing Administration's Common Procedure Coding System, the MCFL classifications are defined as the following: K0 includes individuals determined to be unable to safely ambulate with a prosthesis independently and the addition of a prosthesis will not enhance their quality of life.[8] The next level, K1, is defined by a person who has the potential to ambulate safely and independently with a prosthesis but mostly stays and ambulates within their own home. K2 ambulators are expected to have the ability to maneuver around common environmental barriers like curbs or unleveled ground. The difference between

K2 and K3 is that K3 ambulators are expected to be able to ambulate with variable cadence while K2 ambulators cannot. Lastly, K4 ambulators include individuals that have motor function which exceeds the basic ambulation requirements and are more conducive to an active lifestyle. Normally, individuals who fall into this category were previously athletes, younger individuals, and/or highly active prior to amputation.

Researchers have found that the AMP score ranges for each K-level are appropriate and accurately predict K-level.[9] Furthermore, evidence has shown the AMP test to be a reliable and valid measure to assess a lower limb amputee's ability to ambulate.[3] Studies have shown that the AMPnoPro is a valid predictor of mobility outcome using a prosthesis in lower limb amputees as well.[10] Since K-level is used to determine insurance reimbursement for prosthetic components, the designation of K-level is extremely important to ensure each patient receives the proper components that will meet the demands of their activity level and lifestyle. Prosthetic components are also designated to different K-levels through a systematic process that has been evaluated and accepted as an appropriate classification method.[11]

Despite research validating the AMP test, many prosthetists still do not rely on it to determine k-level and instead determine it clinically without completing the AMP test. The American Academy of Orthotists and Prosthetists does not currently have a gold standard for establishing K-levels and many prosthetists believe that the AMP test is not enough to determine the rehabilitation potential of a new amputee.[12,13] Therefore, clinicians often use multiple outcome measures to provide a broader perspective of a patient's functionality. The other two measures that will be evaluated in this study are the 10mWT and TUG test. Both of these test the self-selected and maximal speeds for completion of each test. The 10mWT strives to determine the walking speed of an individual across a 10-meter distance. The TUG test asks the patient to

transition from a sitting to standing position, walk 3 meters, turn, walk back to the starting point and return to a seated position.[14] The 10mWT and TUG test are used as an outcome measure for many patient populations beyond amputees including stroke patients, SCI patients, patients with Parkinson's disease, TBI patients etc.[15, 16] They have both been validated as appropriate measures to asses walking speed, balance and general functional ability in other patient populations.[15, 16]

Though this study will not examine self-reported outcome measures, many are currently used to assess amputee's confidence level in their mobility. Some examples of self-reported measures include the Activities-specific Balance Confidence Scale (ABC), Patient Reported Outcomes Measurement Information System (PROMIS-29), or the Prosthetic Limb Users Survey of Mobility (PLUS-M). Typically, these are administered by paper or electronically and simply include questions or items to be ranked and answered by the patient. Their responses are then recorded and their overall score is determined. The ABC and PROMIS-29 can be used for various patient populations while the PLUS-M is specific to prosthesis users. These measures provide more information from the perspective of the patient on his or her rehabilitation progress. Performance-based outcome measures are a method to objectify the perception and experience of a patient regarding their progress. It is possible that the patient's rehabilitation is being impeded by a stressful home life or mental illness, something of which a clinician should be aware. Researchers have found evidence to believe that the PLUS-M is a valid self-reported measure for lower limb amputees.[17] The ABC test was found to be the sixth most used measure by prosthetists out of the 20 tests surveyed.[18] Many studies evaluate both self-reported measures and performance-based measures. Gailey et al. 2012 used both to determine functional difference between four different prosthetic feet.[19] Kark 2016 also used both types of measures to quantify

prosthetic gait deviations.[20] Initially, this study aimed to also assess a self-reported measure but the clinic our data come from has only recently implemented the use of the PLUS-M and PROMIS-29. Thus, there was not sufficient data to include in this study.

Despite there being many outcome measures already available to assess prosthetic patients, many are currently being developed and/or researched to use with this patient population still. The goal is to increase the number of different aspects of mobility that can be evaluated. For example, most current tests that asses gait do so by examining linear motion. The Figure-of-8 walking test combines and assesses both linear and circular walking patterns since the biomechanics of walking in a straight line versus walking in a curved path are different.[21] Realistically, people cannot travel to any given destination by solely walking in a straight line. This test and many others aim to expand functional assessment abilities and make them more applicable to real life.

All of these measures have potential to contribute to the care of prosthetic patients in many ways. The first is using outcome measure results to track progress. It is a quantitative method to monitor improvements functionally and also psychologically throughout the rehabilitation process. Some patients may find encouragement in having tangible evidence of their progress which could increase patient compliance and benefit both the patient and clinician. Additionally, once normative data has been established for each measure specific to the prosthetic patient population, these tests can be used as a means of comparison to ensure each patient is on track and is performing at the proper level during each stage of their rehabilitation. Outcome measures may also be used as a substitution for other clinical assessment methods like 3D gait analysis which might be less convenient or quick to perform in a clinical setting.[22]

Although many prosthetists do currently utilize these measures in clinic, there are still many doubts about which measures are the most useful, the protocol for what stage of rehabilitation they should be administered, and the confidence of clinicians to administer these tests and use the results.[18, 23] Some studies have tried to compare similar outcome measures to confirm which is better. One study compared the Six Minute Walk test (6MWT) to the Two Minute Walk test (2MWT) and found that the 2MWT is highly predictive and correlated to the 6MWT (R^2=0.91).[24] Thus, the 2MWT is just as useful in assessing walking distance as the 6MWT but saves time in clinic to administer. Additionally, researchers have found that 62% of prosthetists do not use outcome measures routinely partly because they do not feel confident in administering the tests.[18] The study found that after training, confidence levels increased which may indicate the need to improve or increase the volume of training regarding clinical outcome measures. Of the prosthetists who did report using them regularly, the primary reason was to justify prosthetic components.[18] There is a need for increased training of clinicians and a routine protocol for outcome measure use. Currently, research studies similar to this one aim to uncover more information to establish an effective protocol that is realistic and takes advantage of the benefits of outcome measures.

The outcome measures assessed in this study were chosen because the clinic from which the data was obtained primarily uses these measure with their patients. The parameter of gender was determined based off of normative data that has been established for other patient populations that is separated by gender.[6,7] Initially, this study aimed to separate the data by age as well but the sample size was inadequate to do so. Since K-level is a big determining factor unique to the patient population of prosthesis users and has been proven to be a valid measure of functional ability, the normative data will be organized by this classification. Currently,

normative data for prosthetic patients has yet to be established for the 10mWT and the TUG test in such detail.[6,7] Previous studies have found walking speed averages for amputees but this data was not gender nor k-level specific. One of the more recent studies found the average walking speed for unilateral transtibial amputees to be 1.36 m/s. The speed for unilateral transfemoral was determined to be 1.22 m/s and bilateral transfemoral was 1.12 m/s.[25] Another study determined the average walking speed for elderly male transtibial amputees to be 1.20 m/s but did not report any results for females as they were not studied.[26] There was no further demographic breakdown beyond amputation level in the first study. The purpose of this study is to create normative data for the 10mWT and the TUG test based on K-level and gender and confirm the correlation between all three outcome measures when used to assess prosthetic patients.

Methodology

This retrospective study was reviewed and approved by the IRB at the University of Florida. It is based off of data provided by an orthotics and prosthetics clinic located in Gainesville, Florida. The data is from patients seen at their clinic from January 1, 2012 to April 5, 2017. All outcome measure results were completed at their clinic and administered by an individual trained to do so. When obtaining the data, the following information was requested: patient ID, age, gender, amputee level, reason for amputation, time since amputation/date of amputation, AMP test results (K-level) and date of test, 10mWT results and date of test, and TUG test results and date of test. Furthermore, the inclusion criteria consisted of patients who had an amputation at the level between knee and ankle and had a verified k-level designation based off of completion of the AMP test. In some scenarios, clinicians will assign k-level to a patient based on their knowledge and experience working with the patient without actually

completing the AMP test. Both AMPPro and AMPnoPRO results were used in this study without distinguishing between k-levels determined from AMPPro or AMPnoPRO. The data was de-identified prior to receiving it and was in the format of a Microsoft Excel spreadsheet.

The data included all patients from this clinic so we then made sure to screen out orthotic patients and prosthetic patients who were not transtibial amputees. The next step was to ensure they met the inclusion criteria previously listed. A data collection sheet was completed to organize the testing results of each patient and their corresponding demographics. A few patients have multiple test results due to completing the outcome measure tests at different time points throughout the process of their prosthetic intervention. In these cases, multiple test results for a single patient were used in analysis as separate data points. A majority of data points came from patients who completed all three outcome measures on the same day.

Analysis was completed with the software Statistical Package for the Social Sciences (SPSS) and Microsoft Excel. Descriptive statistics, One-way ANOVA with Tukey post-hoc tests, and correlational tests were run to determine the interaction between the AMP, TUG, and 10mWT while attempting to establish normative values of these outcome measures for the transtibial amputee patient population.

Results

There were 91 patients included in this study with 16, 39, and 36 patients included for the K2, K3 and K4 groups respectively. There was a gender discrepancy within the sample with 67 males and only 24 females. These demographics are further represented in Table 2. Reasons for amputation and time since amputation could not be reported because not every patient that was included in this study had a documented reason for amputation or date of amputation. Unfortunately, our data only included two data points for the K1 group, so data analysis was not

completed for this group. Furthermore, patients that fall in the K0 group, by definition, are unable to ambulate safely with a prosthesis thus they do not have any 10mWT or TUG test results at all.

The mean values for the 10mWT and the TUG test are separated by gender and k-level as shown in graphs 1-4 and presented in table 3. As expected, the walking speeds determined from the 10mWT increase as k-level increases with both maximum and self-selected speeds, and the TUG times decrease as k-level increases with maximum and self-selected speeds. Furthermore, these trends are still seen once the data has been separated by gender. One-way ANOVA results indicate an overall significant difference between K-levels for the 10mWT maximum ($F=14.24$, $p<0.01$), the 10mWT self-selected ($F=25.850$, $p<0.01$), and the TUG self-selected tests ($F=12.031$, $p<0.01$), but not between K-levels for the TUG maximum test ($F=1.99$, $p=0.144$). Tukey post-hoc tests indicate a non-significant difference between K3-K4 levels in the TUG self-selected test ($p=0.161$).

The correlation coefficient between k-level and the 10mWT is positive and significant ($p < .01$) for both maximum and selected speeds, and the correlation coefficient between k-level and the TUG test is negative for both maximum and selected times. The correlation for TUG self-selected speed is significant ($p < .01$), but the correlation for TUG maximum speed is not significant at all. This study provides evidence to support a strong correlation between k-level, 10mWT results, and TUG test results. The average age for each k-level is as follows: 60.5 years for K2, 52.1 years for K3, and 45.9 for K4. The data suggests that age is correlated with k-level and thus functional ability with a correlation coefficient of -.34 which is also significant ($p < .01$). All correlation values are presented in table 4.

Discussion

The data obtained for this study includes k-levels, 10mWT, and TUG test results from 91 separate patients. Using descriptive statistics, means and standard deviations were calculated for both genders at each k-level for the 10mWT and TUG test for both self-selected and maximum speeds/times. The results are displayed in table 3. As expected, each performance measure improved across k-levels with walking speeds increasing and time to perform the TUG test decreasing, respectively. However, based on the low sample size within each K-level, differences between k-levels were not statistically significant based on the TUG maximum times, nor between the K3 and K4 groups for the TUG self-selected times. These results indicate the TUG self-selected test may provide stronger evidence to classify functional ability rather than the TUG maximum test as patient self-selected times differentiated K-levels better than their maximum times. The data also showed large standard deviations that are most likely due to an insufficient sample size for each group. The data used in this study comes from a single orthotics and prosthetics clinic thus it is a convenience sample and may not be deemed an accurate representation of the general population of lower limb amputees. It appears that the descriptive data presented in this study is appropriate for use in differentiating transtibial amputees across k-levels 2-4 based on results from the 10mWT (both maximum and self-selected speeds) and the TUG self-selected test, but not for the TUG maximum test.

Beyond the normative data, there were a few statistical findings among this study that did stand out. The calculated standard deviation for males at the K3 level for TUG Max was abnormally large and could be considered an outlier compared to other groups' standard deviations. A possible explanation may be an inadequate sample size. TUG max was also the only outcome measure that did not correlate with k-level significantly while 10mWT max,

10mWT self-selected and TUG self-selected all had significant correlations to k-level ($p < .01$). This may be due to an insufficient sample size specifically for TUG max across all k-levels. TUG max did have the smallest number of data points ($n = 65$) of the four examined measures. Another interesting find is that for both self-selected and maximum times for the TUG test, males on average had slower scores than females at every k-level. For the 10mWT, this gender difference was not seen. Females averaged having TUG maximum times and TUG self-selected times that were 3.56 seconds and 5.11 seconds faster than males respectively. The gender difference appeared to diminish as k-level increased. A study found that the minimal detectable change for TUG test results among lower-limb amputees is 3.6 seconds, thus the gender difference seen in this study may be worth investigating further.[27]

The results of this study support previous studies in confirming the correlation between the outcome measures examined. K-level determined from the AMP test, the 10mWT, and the TUG test correlate with age as expected showing greater levels of functionality for younger prosthesis users. Also, subjects in higher k-levels have faster walking speeds and shorter TUG test times which is to be expected for more functional individuals. Thus this study provides additional evidence to say that all three of these measures are reliable to use in the prosthetic field. Although, further research is still needed to confirm reliable normative values for this patient population.

Once normative data is conclusively determined, clinicians and patients will have a better idea of where they should score on the respective functional tests once their k-level is determined. These levels provide insight into a patient's potential to reach a certain functional level over time when using a prosthesis and are an effective tool for creating goals with a patient. The acclimation period for a new amputee comes with many setbacks as he or she learns how to

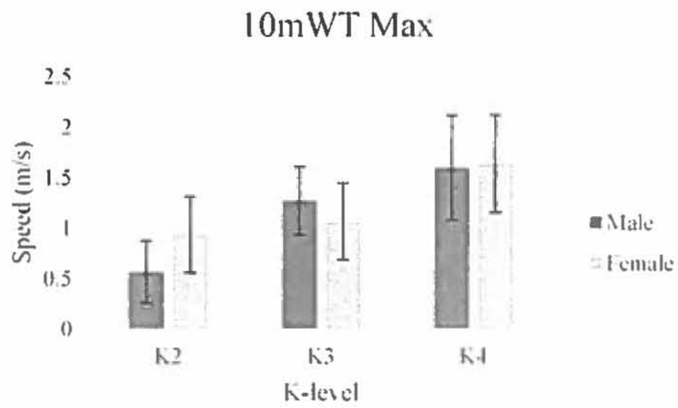
ambulate while using a prosthesis. By understanding where other prosthesis users lie, normative data may help to increase patient motivation and compliance resulting in benefits for the patient and clinician. Lastly, establishing normative data may also help to provide additional evidence to insurance companies to specify which prosthetic components an individual requires which will ensure prosthesis users are able to be as functionally independent as their personal limitations allow.

Conclusion

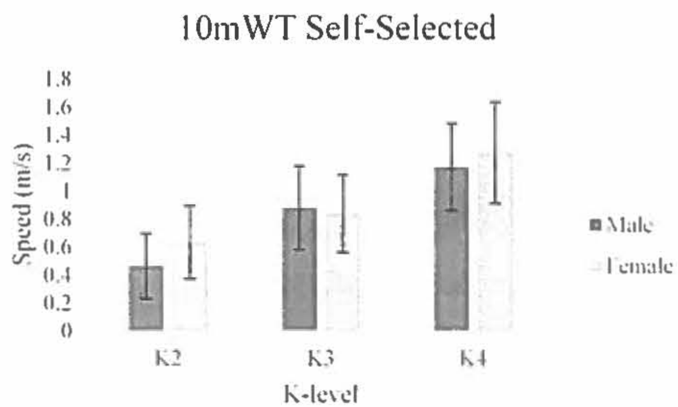
Unfortunately, the goal of this study was not met due to inconclusive results most likely because of inadequate sample sizes. Despite this failure, the expected trends were present within the data of this study. K-level is shown to be directly correlated to walking speed and indirectly correlated to TUG test times. There is also evidence to say that functional ability deemed by the AMP test decreases as age increases among adults. More research may be beneficial to determine differences between male and female prosthesis users as this study did find an unexpected trend among TUG test results. Additionally, the creation of reliable normative data requires further investigation. As expected, this study confirmed the correlation between the AMP test, 10mWT, and the TUG test, but more research is warranted to learn how to best use and apply these measures and their results in clinic to optimize the care and rehabilitation for transtibial prosthesis users.

Appendices

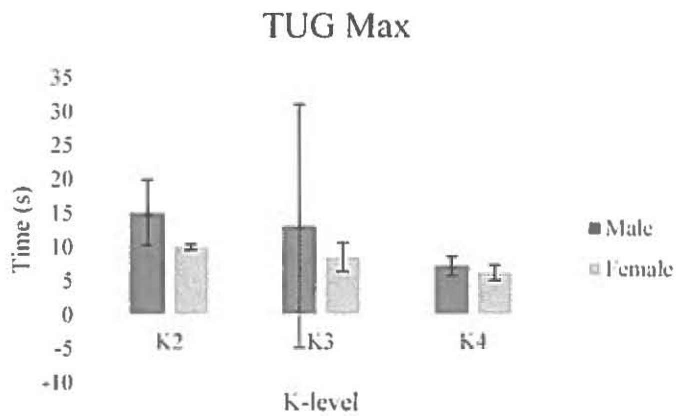
Graph 1. Mean Values for 10mWT Max.



Graph 2. Mean Values for 10mWT Self-Selected.



Graph 3. Mean Values for TUG Max.



Graph 4. Mean Values for TUG Self-Selected.

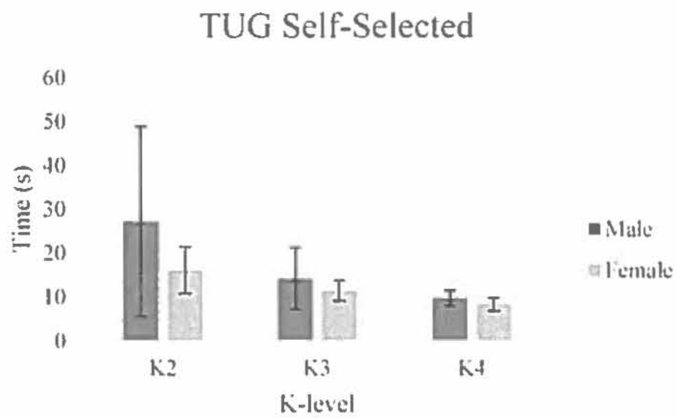


Table 1. AMP Score Ranges for K-level designation.

	AMPnoPRO	AMPPro
K0	0-8	N/A
K1	9-20	15-26
K2	21-28	27-36
K3	29-36	37-42
K4	37-43	43-47

Table 2. Demographics by K-Level.

K-level	Gender		Mean Age (years)
	Male	Female	
K2	10	6	60.5
K3	28	11	52.1
K4	29	7	45.9
All	67	24	52.8

Table 3. Mean Values for 10mWT and TUG test by K-level and Gender.

K-Level	Gender	10mWT Max (m/s)	10mWT Self-Selected (m/s)	TUG Max (s)	TUG Self-Selected (s)
K2	Male	0.57 (0.306)	0.46 (0.234)	15.00 (4.791)	27.21 (21.618)
	Female	0.93 (0.375)	0.64 (0.261)	9.93 (0.451)	16.10 (5.312)
K3	Male	1.27 (0.337)	0.88 (0.298)	13.1 (17.883)	14.18 (7.086)
	Female	1.06 (0.379)	0.84 (0.276)	8.45 (2.093)	11.36 (2.300)
K4	Male	1.60 (0.519)	1.17 (0.311)	7.15 (1.411)	9.71 (1.810)
	Female	1.64 (0.481)	1.27 (0.362)	6.18 (1.123)	8.30 (1.471)

Represented as mean (SD).

Table 4. Summary of R-values from Pearson Correlation Test

All K-levels	10mWT Max	10mWT Selected	TUG Max	TUG Selected
K-level	.547**	.629**	-0.229	-0.479**
10mWT Max		.845*	-0.292*	-.669**
10mWT Selected			-.268*	-.700**
TUG Max				.302*
K2				
10mWT Max		.968**	-.976*	-.947
10mWT Selected			-.910*	-.799**
TUG Max				.946**
K3				
10mWT Max		.898**	-.308	-.307
10mWT Selected			-.151	-.450*
TUG Max				.177
K4				
10mWT Max		.692**	-.612**	-.550**
10mWT Selected			-.685**	-.650**
TUG Max				.919**

*-Significant ($p<0.05$); **-Significant ($p<0.01$)

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