TITLE: Assessing Mobility for Persons with Lower Limb Amputation: The Figure-of-Eight Walk Test with the Inclusion of Two Novel Conditions

Abstract

Purpose: To investigate the internal consistency, convergent and known-groups construct validity of the Figure-of-Eight Walk Test with two novel conditions in persons with lower limb amputation, and to examine differences in walking performance between the three conditions within a group of persons with transtibial amputation and transfemoral amputation/knee disarticulation.

Materials and methods: 50 adults with unilateral amputation participated, 28 of whom had undergone a transtibial amputation and 22 a transfemoral amputation/knee disarticulation. Three Figure-of-Eight Walk Test Conditions were investigated: 1) walking at a self-selected walking speed, 2) walking while carrying a tray with two cups of water and 3) walking on uneven terrain. Internal consistency was evaluated using Cronbach's alpha. Convergent construct validity was examined by analysing the relationship between the Figure-of-Eight Walk Test parameters and performance-based parameters (Amputee Mobility Predictor, Ten-Meter Walk Test, Six-Minute Walk Test) and self-report measures (Prosthetic Limb Users Survey of Mobility, Activities-specific Balance Confidence Scale) using Spearman's rank-order correlations. Known-groups construct validity was assessed by comparing the Figure-of-Eight Walk Test parameters based on anatomical level of amputation. Friedman's test and posthoc analysis was used to examine differences between the walking conditions within each group.

Results: Cronbach's alpha coefficients of the Figure-of-Eight Walk Test parameters for all three conditions ranged from .89 to .99. The Figure-of-Eight Walk Test time and steps parameters demonstrated moderate to good correlation (r = -.50 to -.77) for performance-

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based mobility measures. The correlations were stronger during Condition 3 in comparison with the original Figure-of-Eight Walk Test. The correlation was fair to good (r = -.41 to -.57) for the self-report mobility measures. Comparison between groups showed a difference between transtibial and transfemoral amputation/knee disarticulation participants when it comes to the Figure-of-Eight Walk Test time and smoothness parameters in Condition 2 (p < .05). Comparison between walking conditions within each group, showed significant differences in the Figure-of-Eight Walk Test parameters in the two novel conditions in comparison with the original Figure-of-Eight Walk Test. The Figure-of-Eight Walk Test and the novel conditions demonstrated excellent internal consistency, good convergent construct validity and evidence of known-groups construct validity. Future studies should further develop and standardise the smoothness scale to better quantify walking performance and assess the responsiveness and reliability (inter-rater and intra-rater) of the Figure-of-Eight Walk Test (time and steps) and the novel conditions, while studies on known-groups validity should include persons with a wider mobility range.

Keywords: Artificial limbs; prosthetic mobility; outcome measures; rehabilitation; walking; dual-task.

Short title: The Figure-of-Eight Walk Test and two novel conditions.

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Introduction

The goal of rehabilitation for persons with lower limb amputation is often to regain mobility [1, 2, 3], hence research on mobility outcome measures is particularly important. Mobility in the real world is more complex than merely walking straight forward and can be seen as forms of movement performed within an environmental situation, i.e. the setting or context in which the activity is performed [4]. Being able to navigate in different environmental situations is a multi-task activity that requires planning and attention [5]. While walking, people are often required to perform two or more activities simultaneously, hence increasing attentional demands (e.g. carrying a load or talking on the phone). Cognitive flexibility and the ability to adapt to changing environmental situations is therefore crucial to successful ambulation [6, 7, 8, 9].

Walking with a prosthesis is physically and cognitively demanding [10]. Many persons with lower limb amputation have reported the need to "concentrate on every step" and this may reflect increased use of cognitive resources [11]. Cognition has an impact on walking performance, and the current literature on lower limb amputation recognises this relationship [12, 13, 14, 15, 16]. Hence, it is important that outcome measures reflect the complexity of mobility in daily life by including both cognitive and environmental dimensions, and at the same time are easy and quick to administer in a clinical setting [6]. There are various outcome measures that evaluate mobility among persons with lower limb amputation [11, 17, 18], however, there is little consensus on which outcome measures to use when evaluating mobility in persons with lower limb amputation [19]. Daily activities often require simultaneously performance of two activities, however few of the measures that are in regular use encompass the variety of cognitive and environmental challenges that persons with lower limb amputation encounter in daily life. Dual-task tests, which evaluate an individuals' ability to perform two activities simultaneously, have commonly been used to indirectly examine the interaction between cognition and walking performance in persons with lower limb amputation. Various cognitive tasks like serial subtractions or the Stroop test have been used together with walking tasks in dual-task assessments among persons with lower limb amputation [6, 7, 20, 21, 22]. The results indicate that adding a concurrent cognitive task decreases performance in both walking and cognitive performance [22] and a decrease is observed regardless of level of amputation, or time since amputation [13]. However, to our knowledge, these dual-task tests have not been validated in persons with lower limb amputation. In addition, a recently published review [11] concluded, that there is a need to assess the interaction between cognition and walking performance under challenging walking conditions that better reflects the situations faced by amputees in their daily lives and community environments.

Outcome measures for persons with lower limb amputation must address the frequency and contribution of turns in day-to-day pursuits[23, 24]. The ability to turn, while avoiding barriers or navigating the streets, are common and frequent situations in community mobility [25, 26] that require cognitive processing. Turning is also involved in many everyday activities, and is especially relevant in household mobility such as walking from room to room and turning away from a table [24]. Furthermore, curved-path walking involves complex motion strategies, thereby involving different cognitive processing than straight-path walking [26]. The body´s centre of mass shifts to the inner foot with an increase in stance time, which is challenging for people with lower limb amputation [5, 23, 26]. The increased time and number of steps needed to perform a turn is related to an increased risk of falling [27], thus a performance-based test that incorporates turns and curved-path walking may be a clinically relevant test of mobility for persons with lower limb amputation.

The Figure-of-Eight Walk Test (F8W) developed by Hess et al. [5] is a test of curved-path walking designed to simulate the complexity of walking in daily life. To our knowledge, this test has not yet been used for persons with lower limb amputation, thus the usefulness of the F8W as a measure of mobility in persons with lower limb amputation needs to be investigated. In addition, we propose two novel conditions of the F8W with a view to capturing more of the environmental and cognitive challenges persons with lower limb amputation experience in their daily pursuits. These novel conditions are inspired by the description of environmental dimensions in prosthetic mobility, originally described by Hafner et al. [4]. These environmental dimensions are terrain, distance and time, obstacles, attentional demands, external loads and ambient conditions. The classification of these dimensions is based on results from focus group interviews and describes mobility from the perspective of persons with lower limb amputation. The two novel conditions are both performed in a figure-of-eight walking pattern: carrying a tray with two cups filled with water and walking on soft and uneven terrain. To carry a load on a tray is an activity with increased attentional demand as the tray partly blocks both the view to the ground and the prosthesis when walking. Carrying objects has been reported to limit the mobility of persons with lower limb amputation due to the limited view of the prosthesis and reduced balance, and is thus considered a challenging situation [4, 19]. Walking on uneven terrain may represent another type of challenge that requires increased attention for persons with lower limb amputation due to the need to compensate for the limited afferent input when walking on different surfaces [7]. Walking outdoors, which often requires the ability to walk on uneven terrain, is highlighted by persons with lower limb amputation as an important activity that facilitates community mobility and increases quality of life [4, 9, 19, 20, 28]. These two novel environmental conditions are not captured in other performance-based mobility outcome measures for persons with lower limb amputation [2, 3, 23, 29, 30, 31, 32]. The sustained attentional demands in both carrying a tray and walking on an uneven, non-predictable surface require continuous cognitive processing for motor control.

Although a number of mobility scales exist [17, 33], they are limited in their ability to reflect the demands associated with turning in combination with added challenges like carrying a load or walking on uneven terrain. Other measurements that include turning (e.g. the Timed Up and Go (TUG) [23, 34] and the L-Test and modified L-test version [6, 35]) for persons with lower limb amputation do not include more complex environmental dimensions of this kind. In addition, the TUG test does not include counter-clockwise turns, and the L-test may require too much space in a clinical setting [18]. Thus, there is a need for a performance-based mobility test that investigates complex path walking in different environmental dimensions that may require the use of a greater proportion of physical and cognitive capacities. Such a test may provide meaningful information about the mobility of persons with lower limb amputation in everyday situations [5, 6].

The objective of the current investigation was thus to propose two novel conditions in addition to the F8W and to examine whether there was a difference in performance among the three walking conditions within a group of persons with transtibial amputation and transfemoral amputation/knee disarticulation, respectively. Furthermore, the objective was to evaluate the reliability (internal consistency) and convergent and known-groups construct validity of the F8W and the two novel conditions.

We hypothesised that the F8W and the novel conditions would have excellent ($\alpha > .80$) internal consistency and good ($r > .50$) convergent and known-groups construct validity.

Secondly, we hypothesised that the F8W time and the number of steps would show a negative correlation, and smoothness scores would show a positive correlation with performance-based measures of mobility. We also hypothesised that the self-report measures of mobility would show lower correlation compared to the performance-based measures of mobility [36]. Lastly, we hypothesised that the F8W parameters would be able to discriminate between persons with lower limb amputation based on amputation levels. We expected that persons with transtibial amputation would perform the F8W tests in less time, with fewer steps and greater smoothness than those with transfemoral amputation/knee disarticulation.

Materials and Methods

Study design

The present study is cross-sectional and part of an observational study examining cortical activity during prosthetic ambulation. The participants were recruited from: (1) local workshops and rehabilitation centres through flyers, (2) Facebook groups for two user organisations and (3) friends, family and peers. The Regional Committees for Medical and Health Research Ethics approved the study (2015/1245), and it was performed according to the principles of the Declaration of Helsinki. All participants signed an informed consent form prior to participation.

For instrument validation, samples larger than 100 persons are recommended and considered excellent, and a sample size of 50 is considered to be good [37]. However, due to the limited number of prosthetic users available for this study, we performed a prior power analysis to identify the minimum sample size necessary to yield results of sufficient power and confidence for the known-groups construct validity assessment. The power analysis was conducted based on values for walking speed (no walking aid) from persons with transfemoral amputation and transtibial amputation [38]. The mean walking speed (SD) was: 65.64 m min^{-1} (4.18) and 79.02 m min^{-1} (11.26) for persons with transfemoral amputation and transtibial amputation, respectively, with an estimated difference of 13.4 m min^{-1} between the groups. Setting the alpha to .05 and the desired power to 80%, power analysis (Stata/SE 14.2 for Windows, College Station, TX, USA) estimated a minimum sample size of 10. Consequently, to establish balance between the requirement for validation studies and the power analysis, a sample size of 20 persons with transfemoral amputation/ knee disarticulation and transtibial amputation, respectively, was considered appropriate for examining known-groups construct validity.

Inclusion criteria: (1) age over 18 years, (2) ability to walk without an assistive device for at least 500 meters, (3) unilateral lower limb amputation at transtibial, transfemoral or knee disarticulation level, (4) have walked with a prosthesis for at least six months. Exclusion criteria: no comorbidities impacting the ability to complete the protocol. Not able to understand written or spoken XXXX, which is used to provide instructions for performing the various tests.

Procedure

All tests were conducted in the Motion Analysis Laboratory, Oslo Metropolitan University. The participants all answered questions regarding sociodemographic, health information, amputation and prosthetic history.

After completing the F8W, the participants completed two self-report instruments on mobility, i.e. the Prosthetic Limb Users Survey of Mobility (PLUS-M) and the Activities-specific Balance Confidence (ABC) scale. In addition, performance-based measures of mobility, i.e. the Amputee Mobility Predictor (AMP), Ten-Meter Walk Test and Six-Minute Walk Test were performed. These selected outcome measures were assumed to be the best for establishing the convergent and known-groups construct validity of the F8W and the novel conditions [3, 19, 29, 39]. However, mobility in daily life is a complex multidimensional construct [19], which makes it difficult to measure in a single test. Hence, we chose both performance-based and self-reported outcome measures as validation measures for this study in the absence of a “gold standard” for assessing mobility in persons with a lower limb amputation. Although we chose different validation measures, several measures were not used, such as the Timed Up and Go test or L-test. Similar to the F8W, both of these tests include turns (two and four turns, respectively), but they also include the task “to rise from a chair”, which is not included in the F8W. The Six-Minute Walk Test, which is used as a validation test in the current study, was performed using a 15-metre course and thereby included several turns, which might resemble the F8W. In addition, the original F8W was validated using gait speed among other established measures of gait for older adults. Hence, we chose gait speed as one of the outcome measures together with other mobility outcome measures often used to assess mobility in persons with lower limb amputation (AMP and PLUS-M). Furthermore, the PLUS-M includes the task “carrying an object” (items 5 and 6) and “walking on uneven terrain” (item 12), which is not included in other walking tests. Accordingly, we believe that the validation tests included are appropriate measures for the current study.

One rater (JS) administered all testing procedures.

F8W conditions

Three test conditions were investigated. Condition 1: ordinary F8W (figure 1) (insert figure 1) with self-selected walking speed. Condition 2: F8W carrying a tray (44 cm x 33 cm, weight 1 kg including cups) with two cups (diameter 8 cm, height 9 cm) placed 15 cm apart measured from the middle of the tray and filled with cold water to 1 cm from the top. The tray was carried with both hands and carried directly in front of the participant. The participants were instructed to avoid spilling any water while walking in order to increase the cognitive load of the task. Condition 3: F8W on uneven and soft terrain simulating a non-predictable walking environment. The uneven and soft terrain used in Condition 3, consisted of six foam mats (185 cm long, 60 cm wide and 1.5 cm thick, Airex Coronella, Airex AG, Switzerland) placed next to each other in a rectangle (3 x 2). Two cones were placed centrally on top of the mats 152.4 cm apart as reported by Hess et al [5]. Sixteen slices of foam mats (60 x 9 x 1.5 cm) were placed and taped firmly underneath the six larger mats with eight slices around each of the two cones. A slice sized 60 x 32 x 1.5 cm was placed beneath the start position and the exact placement of the other slices around the cones are shown in Figure 1 and described in the figure caption. Before performing the F8W, the participants were instructed to: (1) stand midway between the two cones, (2) when signalled, start walking at their self-selected walking speed in a self-selected direction in a figure of eight pattern around the cones. The direction was self-selected in each trial. The time started from when the participants started to take their first step and stopped when their leading foot crossed the starting position.

The F8W time (measured with a stopwatch and timed to the nearest 100th of a second), the number of steps (rater counted) to complete the task, as well as the smoothness of walking, were recorded for each condition. The three-item smoothness scale described by Hess et al. [5] was used to score the walking: Completing the F8W without 1) stopping, 2) hesitating or

3) changing the speed. Each item was scored as either “0” (any difficulty) or “1” (no difficulty), for a total smoothness score ranging from 0 (not smooth) to 3 (smooth).

Each test condition was repeated five times (trials) with a rest period of 40 seconds between trials and 60 seconds of rest between each condition. The sequence of conditions was randomised. There are no recommendations relating to the number of trials or the duration of the rest period, and we decided to conduct this number of trials to increase confidence in calculating an accurate average according to the central limit theorem [40]. Each of the F8W parameters were averaged over the five trials.

Performance-based outcome measures

The AMP consists of 20 different items and is an instrument designed to measure the mobility potential of people with lower limb amputation. The AMP has excellent intra-rater (ICC .96 and .97) and inter-rater (ICC .99) reliability, known-groups construct validity, and convergent construct validity in people with lower limb amputation [29]. The AMP is scored from 0 – 47, where higher scores indicate better mobility.

A Ten-Meter Walk Test was used to assess the self-selected walking speed [30, 41]. Support for concurrent and convergent validity has been reported, as well as excellent intra-rater reliability (*r* between .83 and .98) [41, 42]. The participants walked 10 metres at their self-selected walking speed and the time was measured for the intermediate six metres to allow for acceleration and deceleration at either end [30]. The average of three trials was used to calculate the walking speed.

The Six-Minute Walk Test is used to assess endurance during ambulation [30]. The test measures the distance (in metres) a person can walk during a period of six minutes. In people with lower limb amputation, the Six-Minute Walk Test has been found to be reliable, valid, and able to differentiate among functional levels [29]. The test-retest reliability is high, (ICC .94 – .97) [43]. The participants were instructed to walk as quickly as possible (without running) back and forth between two cones (15 metres apart) on a flat, hard surface for six minutes [44]. A 15-metre course was chosen in order to be applicable in the laboratory, and no significant difference has been found between walking courses of between 15 and 50 metres [45]. The test was performed once.

Self-report outcome measures

The PLUS-M 12 item is an instrument used to measure the self-reported mobility of adults with lower limb amputation [46]. The questions assess the participants' perceived ability to carry out actions ranging from household ambulation to outdoor recreational activities [39]. The PLUS-M has excellent test-retest reliability (ICC .9) [47], known-groups construct validity, and convergent construct validity in people with lower limb amputation [39]. The PLUS-M provides a T-score that ranges from 21.8 - 71.4. Higher T-scores correspond to greater mobility.

The ABC scale is a 16-item measure of self-efficacy designed to assess confidence in performing various mobility-related activities that require varying amounts of balance [48]. The ABC scale with a simplified 5-option response format has demonstrated high internal consistency reliability and good construct validity in people with lower limb amputation [49]. The ABC scale scores from 0 to 4 and the total score is the average of the 16 items, where higher scores indicate greater balance confidence.

Statistical analysis

Statistical analyses were performed using IBM SPSS statistics 24 (IBM Corporation, Armonk, NY, USA). Descriptive statistics were used to analyse demographic data. Continuous data in the tables are described with mean and standard deviation when normally distributed, or with median and range when showing a skewed distribution. Categorical variables are presented as numbers and percentages. Score distribution was evaluated for normality using visual inspection of both histograms and Q-Q plots. As the F8W parameters were not normally distributed, nonparametric tests were used to assess convergent and known-groups construct validity. The F8W parameters steps and time were moderately skewed in the direction of a lower score for all three conditions. The F8W smoothness score was moderately skewed in the direction of a lower score for Conditions 2 and 3, respectively, and towards a higher score for Condition 1. Descriptive statistics were used in addition to describe the functional level of the participants on the basis of the results from the AMP, Ten-Meter Walk Test, Six-Minute Walk Test, PLUS-M and ABC. The performance-based and self-report outcome measures were compared between the two groups using Student's t-test.

To identify any significant differences between the walking conditions within each group, we used a Friedman's test. We estimated pairwise posthoc tests using the Wilcoxon Signed Rank Test between all combinations of walking conditions, and used Bonferroni correction adjustment for three multiple tests ($p < .0167$).

Convergent construct validity was evaluated by comparing F8W parameters (time, number of steps, and smoothness scores) to both performance-based and self-report measures of mobility. Spearman's rank-order correlation (ρ) was used to define the bivariate relationships of each of the variables in the F8W scores for the three conditions. The strength of the correlations was evaluated according to established thresholds: Correlations ranging from 0 - .25 = little to no correlation; .25 -.50 = fair correlation; .50 -.75 = moderate to good correlation; > .75 = good to excellent correlation [50]. Moderate to good, and good to excellent correlations (i.e. $r > .50$) were considered evidence of convergent construct validity.

Known-groups construct validity was examined by comparing mean F8W scores (time, steps and smoothness scores) at each condition between persons with transtibial amputation and transfemoral amputation/knee disarticulation, and were further examined using the Mann-Whitney U test. Statistically significant differences ($p < .05$) between groups were considered evidence of known-groups construct validity.

To assess internal consistency reliability, we calculated Cronbach's alphas for each of the F8W parameters (time, steps and smoothness) for each condition. The strength of the Cronbach's alpha coefficient was evaluated as: Excellent > .8; adequate .70-.79; poor < .7 [42].

Results

Descriptive characteristics

The characteristics of the study population are presented in Table 1 (insert Table 1). The mean age (SD) of persons with transtibial amputation was 56 (12) years, and 52 (14) years for persons with transfemoral amputation/knee disarticulation. Most of the amputations had been performed for non-vascular reasons (86%). The mean (SD) number of prescription medications was 1.6 (1.4) for persons with transtibial amputations and 0.9 (1.3) for persons with transfemoral amputation/knee disarticulation. Persons with transtibial amputations were amputated on average (SD) 16 (16) years prior to this investigation, and persons with transfemoral amputation/knee disarticulation on average 22 (18) years prior. All participants wore energy-storing prosthetic feet and sixteen of the persons with transfemoral amputation used microprocessor-controlled knees, while the others used different types of mechanical knees. The median prosthetic use was 15.5 hours/day (range 5-15.5) for persons with transtibial amputation and 14.8 hours/day (range: 5-15.5) for persons with transfemoral amputation.

Information about the functional level is summarised in Table 2 (insert Table 2), which shows the results from the performance-based and self-report outcomes. Twelve per cent scored the maximum values in the AMP and PLUS-M, while four per cent scored the maximum score in the ABC. The comparison of the performance-based and self-report measures of mobility did not show any significant differences between persons with transtibial amputation and transfemoral amputation/knee disarticulation, except for the AMP.

F8W and the novel conditions

The Friedman test revealed significant differences in F8W parameters (time, steps and smoothness) between the walking conditions within the group of persons with transtibial amputation ($p < .001$) and the group of persons with transfemoral amputation/ knee disarticulation ($p < .001$). Posthoc analysis showed a significant ($p < .001$) higher median score in F8W time and steps in Conditions 2 and 3 compared with Condition 1, for both groups, respectively. Both groups showed a non-significant ($p < .0167$) difference in F8W time between Conditions 2 and 3 (persons with transtibial amputation: $p > .51$, persons with transfemoral amputation/ knee disarticulation: $p > .022$). The group of persons with transfemoral amputation/knee disarticulation had a significantly ($p < .004$) higher score in

F8W steps in Condition 2 compared with Condition 3. In contrast, the group of persons with transtibial amputation had a non-significantly ($p > .71$) higher score in F8W steps in Condition 2 compared with Condition 3. There was a significantly ($p < .003$) different F8W smoothness score between all conditions in both groups, respectively.

Convergent and known-groups construct validity

Correlations with the performance-based measures of mobility (Table 3), (insert Table 3) showed, in summary, moderate to good negative correlation ($.5 < \rho < .75$) or good to excellent ($\rho > .75$) negative correlation for all three conditions with F8W time and number of steps, but only fair to moderate positive correlation with smoothness scores ($r = .30$ to $.62$; $p < .05$). Correlations with the self-report measures of mobility showed fair to moderate negative correlation with F8W time and steps ($r = -.41$ to $-.57$; $p < .01$) for all three conditions, and fair correlation with the smoothness score ($r = .03$ to $.45$; $p < .861$).

The results of the group comparisons are summarised in Table 4 (insert Table 4). Significant differences between persons with transtibial amputation and transfemoral amputation/knee disarticulation were found in Condition 1 for the smoothness score and in Condition 2 for the time and smoothness score. Furthermore, a ceiling effect was observed for the F8W smoothness score, ranging from 14 per cent in Condition 3 to 34 per cent in Condition 1, respectively, for all participants. For persons with transtibial amputation, the ceiling effect for the F8W smoothness score ranged from 57 per cent in Condition 1 to 21 per cent in Condition 3, and for persons with transfemoral amputation/knee disarticulation, the ceiling effect was 4.5 per cent in all conditions.

Internal consistency reliability

Table 5 (insert Table 5) shows the Cronbach’s alpha for each of the F8W parameters for each condition. Cronbach's alpha coefficients of the F8W parameters for all three conditions ranged from .885 to .991.

Discussion

The objective of this study was to propose two novel conditions of the F8W for use with persons with lower limb amputation and to examine whether there was a significant difference in the F8W parameters among the three conditions within each group. In summary, the results of the between walking condition comparisons within each group, showed that the F8W parameters in the two novel conditions were significantly different from the original F8W, which suggest that the two novel conditions may pose different challenges to persons with lower limb amputation when compared to the original F8W. The results are comparable to those reported in the dual –task literature, indicating that walking performance decreases when performing two activities simultaneously and the results might underscore the need to assess mobility under challenging walking conditions.

Furthermore, the objective of this study was to examine both the convergent and known-groups construct validity of the F8W with two novel conditions. The main results of the present study showed moderate to good convergent construct validity for F8W times and the number of steps. The study also partly supports evidence of known-groups construct validity based on differences in F8W parameters among persons with different amputation levels.

Convergent construct validity was investigated by comparing F8W parameters for all three conditions with other validated and commonly used mobility outcome measures. As hypothesised, a good correlation (ρ >.5) was observed with the performance-based mobility outcome measures for all three conditions of the F8W for the time and number of steps, demonstrating that the F8W for all three conditions is a valid test of mobility in persons with lower limb amputation. Correlations between F8W (times and steps) and the Ten-Meter Walk Test were comparable to those reported in the literature for older adults [5], persons with Parkinson's disease [51] or stroke [52].

For the self-reported outcome measures, the main results showed only fair to moderate correlations with the F8W times and number of steps for all three conditions. This was not entirely unexpected, given that self-report measures assess the *perception of capability* and/or activity level rather than the actual physical performance. According to Coman and Richardson [36], the correlation between self-report and performance-based outcome measures is generally moderate ($r < .50$), which could explain the weaker correlations between self-reported outcomes and the F8W parameters found in the current study. The correlations between F8W time and PLUS-M were comparable to previous studies, although for Condition 1 and Condition 2, the correlation was fair ($\rho < .5$) [23, 39]. The mean PLUS-M T-score was higher in this study (57 - 59.2, depending on the cause of amputation) compared to the normative T-score of 50 representing the mean mobility for persons with lower limb amputation [39]. In contrast to Hafner et al. [39], the present results show a tendency towards a ceiling effect of the PLUS-M T-score, which underscores that the participants in the current study had a relatively high mobility level. A ceiling effect was also observed for both the AMP and ABC measures. Ceiling effects reduce test variability, thereby limiting the ability to determine correlations [53]. In addition, neither the PLUS-M nor the ABC ask the patient to describe their perceived ability or confidence when walking a curved path or turning, which may also limit the potential to determine correlations.

The smoothness score investigates walking characteristics when stopping, hesitating and changing the speed. The main results of the smoothness score showed fair to moderate correlations with the performance-based and fair correlations with the self-report outcome measures. This may partly be because the time and number of steps required to stop, hesitate, and change speed are already included in the time required to complete the F8W. In addition, the three items in the smoothness score are scored as either "0" (any difficulty) or "1" (no difficulty). However, there is no explanation of what constitutes "difficulty" for each of the three items. The high level of ceiling effect seen in the smoothness score, particularly for the easier walking task (Condition 1), and the limited details regarding the smoothness response format indicate the need for further development and standardisation of the three-item smoothness scale.

Known-groups construct validity was investigated by evaluating differences in the F8W parameters between persons with transtibial amputation and transfemoral amputation/knee disarticulation. Overall, most of the F8W parameters were different ($p < .05$) in Condition 2 between persons with transtibial amputation and transfemoral amputation/knee disarticulation, but this was not the case for Conditions 1 and 3. This may be due to the high mobility level of the participant, the etiology of the amputation and inclusion criterion number two (ability to walk without an assistive device for at least 500 meters), which leads to the inclusion of persons with good mobility performance. None of the participants in the transfemoral amputation/knee disarticulation group had a vascular reason for amputation, and the average walking speed for the participants in this study was 1.3 m sec^{-1}. In contrast to commonly observed differences in walking speed between persons with transtibial amputation and transfemoral amputation/knee disarticulation, there was no difference between these groups in the present study [38]. In addition, the other performance-based tests chosen to validate the

F8W in this study did not show a significant difference between the two groups, except for the AMP. To our knowledge, none of the existing performance-based outcome measures for persons with lower limb amputation assess mobility on uneven terrain; hence, there is a lack of knowledge about this activity for persons with lower limb amputation and a potential difference between persons with transtibial amputation and transfemoral amputation/knee disarticulation. Surprisingly, our results did not show a difference between transtibial amputation and transfemoral amputation/knee disarticulation in Condition 3, walking on soft and uneven terrain. Persons with both transtibial amputation and transfemoral amputation/knee disarticulation lack feedback from the ankle joint, and ankle proprioception may be one of the most important components contributing to balance control during mobility [54, 55]. It has been reported that also persons with transtibial amputation have difficulties with motor control during different mobility tasks [56, 57, 58]. Hence, walking on uneven terrain may be difficult to the same extent for all persons with amputation, regardless of the level, which may have contributed to the similar performances between persons with transtibial amputation and persons with transfemoral amputation/knee disarticulation.

Internal consistency was excellent ($\alpha > .8$) for all F8W parameters and for all three conditions. We could not compare the internal consistency of our results with the original F8W because the original study did not report the values of Cronbach's alpha [5]. However, the results of this study demonstrated an excellent reliability of the F8W and the novel conditions.

This is the first study to describe two novel conditions of the F8W. Assessing mobility by use of the F8W is appealing because the test can be easily administered, and requires little time, cost and minimal equipment. However, the standard setup for Condition 3 requires seven foam mats (six foam mats to create the rectangle (3 x 2) as shown in Figure 1 and one foam mat for the slices) and sufficient space and time for the set up, which may be a limitation. The slices of foam mats beneath the six large foam mats were, however, easily obtained by cutting one Airex mat into slices. The original F8W and the two novel conditions can be used independently, depending of the mobility level of the participant. Since persons with lower limb amputation form a heterogeneous group, it may be advantageous to have tests that can easily be varied and customised in order to evaluate different aspects of mobility. There is a need for performance-based outcome measures that can provide more insight into the performance of further everyday activities and that include the interaction between cognition and functional mobility in a quick and easy way. The results revealed that the correlations were stronger during Condition 3 when compared to the original Figure-of-Eight Walk Test. Evaluating mobility on uneven terrain is especially useful since this test is not included in the walking and mobility tests commonly used for measuring the mobility of persons with lower limb amputation. Although the new conditions of the F8W simulate more of the complexities of mobility in daily life, the test is not able to capture the full complexity of prosthetic mobility [19]. It can, however, provide different and meaningful information about mobility in daily life in a quick and easy way compared to other performance-based outcomes for persons with lower limb amputation.

The present study has some limitations. The sample size of the current study was small (N=50). A sample size of 50 is of good methodological quality when examining validity, while a sample size over 100 is considered excellent [59]. The participant cohort consisted of high-functioning persons with lower limb amputation due to the strict inclusion criteria, and most of the participants had a non-vascular etiology for their amputation. Thus, the study sample is not representative of all prosthetic users, and this may limit the generalisability of the study results. Further studies should include persons who use assistive walking devices or who have lost their limb due to vascular reasons. In addition, the number of steps in the F8W test was counted by the rater and not by a validated pedometer. This could potentially reduce the validity of the step count data, since the rater also assessed smoothness (i.e. the subjective "quality" of the gait). The research was conducted in a laboratory setting, which may not necessarily reflect mobility situations in daily life.

In conclusion, the present study found significant differences in the F8W parameters in the two novel conditions in comparison with the original F8W in both groups. Further, the results showed good convergent construct validity and evidence of known-groups construct validity in persons with lower limb amputation who do not use assistive walking devices. Observed correlations between the time and the number of steps measurements for all three conditions indicate that the F8W is a valid measure of mobility in persons with lower limb amputation. However, the smoothness score showed only fair to moderate correlation, and we recommend further development and standardisation of the three-item smoothness scale. Internal consistency was excellent for all the F8W parameters and for all three conditions. However, it is necessary to further examine the psychometric properties (intra-rater and inter-rater reliability and responsiveness) of the F8W time and steps with the novel conditions. Moreover, we recommend further investigation of known-groups validity, including persons with a lower level of mobility than those included in the current study.

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Declaration of interest statement

The authors declare that there are no conflicts of interest with respect to the research, authorship and/or publication of this article.

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Table 1: Participant demographics and characteristics of persons with transtibial amputation and transfemoral amputation/knee disarticulation.

	Total (N = 50)		**Transtibial amputation** (N = 28)		**Transfemoral/knee disarticulation** (N = 22)	
	n	%	n	%	n	%
Sex						
Female	20	40	12	43	8	36
Male	30	60	16	57	14	64
Education						
Primary school (≤9 years)	8	16	5	18	3	14
High school (10-12 years)	17	34	13	46	4	18
University (13-15 years)	13	26	3	11	10	45
Advanced degree (>15 years)	12	24	7	25	5	23
Employment						
Employed	21	42	11	39	10	45
Student	2	4	0	0	2	9
Retired	11	22	7	25	4	18
"Full sickness benefit"	16	32	10	36	6	27
Amputation etiology						
Cancer	6	12	1	4	5	23
Trauma	27	54	16	57	11	50
Infection	2	4	0	0	2	9
Congenital	6	12	3	11	3	14
Vascular	7	14	7	25	0	0
Other	2	4	1	4	1	5
Comorbid conditions						
Diabetes	3	6	2	7	1	5
Arthritis	4	8	3	11	1	5
Heart disease	9	18	5	18	4	18
Kidney disease	1	2	1	4	0	0
Neurological disease	2	4	1	4	1	5
Lung disease	4	8	4	14	0	0
Cancer	7	14	1	4	6	27

Table 2: Functional level of persons with transtibial amputation and transfemoral amputation/knee disarticulation based on clinical outcome measure scores.

Outcomes	**Transtibial amputation** (N=28)	**Transfemoral amputation/ knee disarticulation** (N=22)	**Student's t-test**		
	Mean (SD)	Mean (SD)	Mean difference	95 % CI	*p*- value
Performance-based					
AMP	43.0 (2.4)	41.7 (2.3)	1.4	.05 – 2.8	**.04**
Ten-Meter-Walk-Test*	1.33 (0.2)	1.28 (0.2)	.05	-.06 – .16	.38
Six-Minute-Walk-Test	482 (97)	474 (99)	7.8	-48.4 – 64.1	.78
Self-reported					
PLUS-M	59.3 (8.0)	57.0 (7.2)	2.2	-2.2 – 6.6	.31
ABC	3.0 (0.7)	3.1 (0.6)	0.1	-.5 – .3	.59

AMP = Amputee Mobility Predictor (Scale 0 - 47), Ten-Meter Walk Test (m sec^{-1}), Six-Minute Walk Test (m), PLUS-M = Prosthetic Limb Users Survey of Mobility (Scale 21.8 - 71.4) and ABC = Activities-specific Balance Confidence (Scale 0 - 4). Clinical data between persons with transtibial amputation and transfemoral amputation/knee disarticulation were compared using Student's t-test. CI= confidence interval. **Bold** numbers are significant values ($p < .05$).

* Missing data for four participants: three persons with transtibial amputation and one person with transfemoral/knee disarticulation.

Table 3: Convergent construct validity: Comparison between F8W parameters for conditions 1, 2 and 3, respectively and performance-based and self-report outcomes of persons with transtibial amputation and transfemoral amputation/knee disarticulation (n=50).

		Performance-based outcomes			Self-report outcomes	
F8W		AMP	Ten-Meter-Walk-Test	Six-Minute-Walk-Test	PLUS-M	ABC
Condition 1						
Time	ρ	-.53**	-.64**	-.71**	-.46**	-.48**
	95% CI	-.73 to -.26	-.80 to -.42	-.85 to -.50	-.65 to -.24	-.67 to -.22
Steps	ρ	-.50**	-.62**	-.67**	-.42**	-.43**
	95% CI	-.70 to -.25	-.80 to -.37	-.83 to -.44	-.66 to -.18	-.63 to -.16
Smoothness	ρ	.46**	.46**	.35*	.17	.09
	95% CI	.21 to .68	.18 to .68	.03 to .59	-.11 to .44	-.19 to .36
Condition 2						
Time	ρ	-.53**	-.54**	-.64**	-.46**	-.41**
	95% CI	-.73 to -.26	-.74 to -.21	-.82 to -.39	-.51 to -.20	-.61 to -.11
Steps	ρ	-.52**	-.52**	-.59**	-.47**	-.43**
	95% CI	-.74 to -.24	-.76 to -.22	-.78 to -.33	-.66 to -.22	-.64 to -.17
Smoothness	ρ	.39**	.41**	.30*	.14	.03
	95% CI	.08 to .64	.10 to .67	.01 to .55	-.17 to .41	-.27 to .31
Condition 3						
Time	ρ	-.53**	-.71**	-.77**	-.57**	-.53**
	95% CI	-.72 to -.28	-.84 to -.51	-.88 to -.59	-.71 to -.37	-.69 to -.31
Steps	ρ	-.55**	-.65**	-.76**	-.51**	-.49**
	95% CI	-.74 to -.30	-.80 to -.43	-.87 to -.60	-.68 to -.27	-.67 to -.26
Smoothness	ρ	.45**	.62**	.58**	.45**	.38**
	95% CI	.17 to .69	.37 to .78	.34 to .77	.21 to .66	.13 to .61

F8W= Figure-of-Eight Walk Test. Condition 1 = walking at a self-selected walking speed. Condition 2 = walking and carrying a tray with two cups filled with water. Condition 3 = walking on uneven and soft terrain. Time = seconds (s) and Steps = number of steps (n) to complete the task, Smoothness = score (0–3). AMP = Amputee Mobility Predictor (Scale 0 - 47), Ten-Meter Walk Test (m sec^{-1}), Six-Minute Walk Test (m), PLUS-M = Prosthetic Limb Users Survey of Mobility (Scale 21.8 - 71.4) and ABC = Activities-specific Balance Confidence (Scale 0 - 4). Spearman's rho correlation coefficients (ρ) and 95 % confidence interval (CI)

* = Significant values $p < .05$

** = Significant values $p < .01$

Table 4: Known-groups construct validity: Comparison of F8W parameters for conditions 1, 2, and 3, respectively between persons with transtibial amputation and transfemoral amputation/knee disarticulation.

		All participants (N = 50)		Transtibial amputation (N = 28)		Transfemoral amputation/ knee disarticulation (N = 22)		Between-groups *p*-values	
	F8W	**Median**	**25% - 75% ranges**	**Median**	**25% - 75% ranges**	**Median**	**25% - 75% ranges**	***p*-value**	**95% CI**
Condition 1	Time	8.9	7.7 – 10.4	8.2	7.7 – 10.0	9.8	8.0 – 10.9	.103	-2.1 – 0.2
	Steps	14.0	12.4 – 15.4	13.8	12.3 – 15.2	14.1	12.9 – 15.9	.348	-2.0 – 0.8
	Smoothness	2.5	1.8 – 3.0	3.0	2.4 – 3.0	1.9	1.6 – 2.6	**< .001**	0.4 – 1.0
Condition 2	Time	10.6	9.4 – 11.8	9.9	8.4 – 11.1	11.6	10.5 – 15.9	**.003**	-2.7 – -0.6
	Steps	15.5	14.2 – 17.5	15.2	13.7 – 17.0	16.9	14.9 – 19.6	.059	-3.0 – 0.0
	Smoothness	2.0	1.0 – 2.8	2.6	2.0 – 2.8	1.5	1.0 – 2.0	**< .001**	0.4 – 1.2
Condition 3	Time	10.4	8.5 – 11.9	9.7	8.1 – 11.6	11.2	8.9 – 12.0	.233	-2.2 – 0.6
	Steps	15.0	13.8 – 17.1	14.9	13.6 – 17.0	15.1	14.0 – 17.3	.710	-1.8 – 1.4
	Smoothness	1.0	1.0 – 1.7	1.4	1.0 – 2.8	1.0	1.0 – 1.3	.161	0.0 0.6

F8W= Figure-of-Eight Walk Test. Condition 1 = walking at a self-selected walking speed. Condition 2 = walking and carrying a tray with two cups filled with water. Condition 3 = walking on uneven and soft terrain. Time = seconds (s) and Steps = number of steps (n) to complete the task, Smoothness = score (0–3). Values are median and interpercentile (25% - 75 %) ranges. Between-groups *p*-values = Differences between persons with transtibial amputation and transfemoral amputation/knee disarticulation were examined using the Mann-Whitney U test, and the 95% confidence interval (CI) was estimated using the Hodges-Lehmann test. **Bold** numbers are significant values ($p < .05$).

Table 5: Internal consistency reliability expressed as Cronbach's alpha (**α**) of the F8W parameters for conditions 1, 2 and 3, respectively in persons with transtibial amputation and transfemoral amputation/knee disarticulation.

	F8W	All participants (N = 50) Cronbach's α	Transtibial amputation (N = 28) Cronbach's α	Transfemoral amputation/ knee disarticulation (N = 22) Cronbach's α
Condition 1	Time	.986	.984	.988
	Steps	.975	.965	.987
	Smoothness	.914	.910	.864
Condition 2	Time	.986	.988	.980
	Steps	.988	.987	.987
	Smoothness	.931	.903	.921
Condition 3	Time	.986	.986	.987
	Steps	.987	.985	.991
	Smoothness	.940	.962	.855

F8W= Figure-of-Eight Walk Test. Condition 1 = walking at a self-selected walking speed. Condition 2 = walking and carrying a tray with two cups filled with water. Condition 3 = walking on uneven and soft terrain. Time = seconds (s) and Steps = number of steps (n), Smoothness = score (0–3).

Figure captions

Figure 1: Figure-of-Eight Walk Test (F8W) illustration.

Schematic illustration of the test layout for the F8W. The arrows illustrate an example of the direction and walking pattern. Cones are represented by the + sign (see main text) and placed 152.4 cm apart. The grey lines illustrate the six foam mats and the red lines illustrate the slices of foam mats used to make the soft and uneven terrain in Condition 3. The slices of foam mats were placed as follows: slices number 2 and 7 were placed 60 cm apart on each side of the cone. The distance between slices number 1 and 2, 2 and 3, 6 and 7 and 7 and 8 was 30 cm, measured from the edge of the foam mats where the numbers are shown on the figure. Slices number 2 and 7 were placed at a 90 degree angle, slices number 1, 3, 6 and 8 at a 45 degree angle and slices number 4 and 5 at a 20 degree angle to the central longitudinal axis between the cones as shown in the figure. Slices number 4 and 5 were placed 30 cm from the cone, respectively, and the distance between these slices were 15 cm. The drawing is not to scale.