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Review

# Clinimetrics of performance-based functional outcome measures for vascular amputees: A systematic review

Amirah Essop-Adam[a,c,*], Enya Daynes[c,e,f], John S.M. Houghton [a,b,c], Andrew T.O. Nickinson[a,b,c], Robert D.S. Sayers[a,b,c], Victoria J. Haunton[a], Coral Pepper[d], Sally J. Singh[c,e,f]

[a] *Department of Cardiovascular Sciences, College of Life Sciences, University of Leicester, Glenfield Hospital, Groby Road, Leicester LE3 9QP, United Kingdom*
[b] *Leicester Vascular Institute, University Hospitals of Leicester NHS Trust, Glenfield Hospital, Groby Road, Leicester LE3 9QP, United Kingdom*
[c] *National Institute for Health Research Leicester Biomedical Research Centre, The Glenfield Hospital, Leicester, Glenfield Hospital, Groby Road, Leicester, LE3 9QP, United Kingdom*
[d] *Library Service, University Hospitals of Leicester NHS Trust, Glenfield Hospital, Groby Road, Leicester, LE3 9QP, United Kingdom*
[e] *Centre of Exercise and Rehabilitation Sciences, Leicester NIHR Biomedical Research Centre-Respiratory, University Hospitals of Leicester NHS Trust, Leicester, United Kingdom*
[f] *Department of Respiratory Sciences, University of Leicester, Groby Road, Leicester, LE3 9QP, United Kingdom*

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ABSTRACT

*Background:* Objective physical performance-based outcome measures (PerBOMs) are essential tools for the holistic management of people who have had an amputation due to vascular disease. These people are often non-ambulatory, however it is currently unclear which PerBOMs are high quality and appropriate for those who are either ambulatory or non-ambulatory.
*Research question:* Which PerBOMs have appropriate clinimetric properties to be recommended for those who have had amputations due to vascular disease ('vascular amputee')?
*Data sources:* MEDLINE, CINAHL, EMBASE, EMCARE, the Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL) and Scopus databases were searched for the terms: "physical performance" or "function", "clinimetric properties", "reliability", "validity", "amputee" and "peripheral vascular disease" or "diabetes".
*Review methods:* A systematic review of PerBOMs for vascular amputees was performed following COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) methodology and PRISMA guidelines. The quality of studies and individual PerBOMs was assessed using COSMIN risk of bias and good measurement properties. Overall PerBOM quality was evaluated with a modified GRADE rating. Key clinimetric properties evaluated were reliability, validity, predictive validity and responsiveness.
*Results:* A total of 15,259 records were screened. Forty-eight studies (2650 participants) were included: 7 exclusively included vascular amputees only, 35 investigated validity, 20 studied predictive validity, 23 investigated reliability or internal consistency and 7 assessed responsiveness. Meta-analysis was neither possible nor appropriate for this systematic review in accordance with COSMIN guidelines, due to heterogeneity of the data. Thirty-four different PerBOMs were identified of which only 4 are suitable for non-ambulatory vascular amputees. The Amputee Mobility Predictor no Prosthesis (AMPnoPro) and Transfemoral Fitting Pre-

*Abbreviations:* 2MWT, 2-Minute Walk Test; 6MWT, 6-Minute Walk Test; 10MWT, 10-metre Walk Test; AMPnoPro, Amputee Mobility Predictor no Prosthesis; AUC, Area Under the Curve; BAMS, Basic Amputee Mobility Score; BBS, Berg Balance Scale; CINAHL, Cumulative Index of Nursing and Allied Health Literature; CLTI, Chronic Limb Threatening ischemia; COSMIN, COnsensus-based Standards for the selection of health Measurement INstruments; CROM, Clinician-Reported Outcome Measures; ECW, Energy cost of walking; FFST, Four Square Step Test; F8W, Figure-of-8 Walking test; FRT, Functional Reach Test; GDI, Gait Deviation Index; GRADE, Grading of Recommendations, Assessment, Development and Evaluations; K Levels, Rating system used by Medicare health insurance (USA) for determining rehabilitation plan or potential; LEMCOT, Lower Extremity Motor Co-Ordination Test; MCID, Minimally clinically important difference; NBWT, Narrow-Beam Walking Test; OLBT, One-Leg Balance Test; PAD, Peripheral arterial disease; PAM, Patient activity monitor; PerBOM, Performance-Based Outcome Measure; PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses; PROM, Patient-reported outcome measure; PROSPERO, International Prospective Register of Systematic Reviews; RMI, Rivermead Mobility Index; R, Correlation co-efficient; SMART goals, Specific, measurable, attainable, realistic and time-bound goals; TFP, Transfemoral Fitting Predictor; TUGT, Timed Up and Go Test

* Corresponding author at: Department of Cardiovascular Sciences, College of Life Sciences, University of Leicester, Glenfield Hospital, Groby Road, Leicester LE3 9QP, United Kingdom.

*E-mail addresses:* aea19@leicester.ac.uk (A. Essop-Adam), enya.daynes@uhl-tr.nhs.uk (E. Daynes), john.houghton@nhs.net (J.S.M. Houghton ), a.nickinson@me.com (A.T.O. Nickinson), rs152@leicester.ac.uk (R.D.S. Sayers), vjh12@leicester.ac.uk (V.J. Haunton), coral.pepper@uhl-tr.nhs.uk (C. Pepper), sally.singh@uhl-tr.nhs.uk (S.J. Singh).

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dictor (TFP) predict prosthesis use only. PerBOMs available for assessing physical performance are the One-Leg Balance Test (OLBT) and Basic Amputee Mobility Score (BAMS).
*Conclusion:* At present, few PerBOMs can be recommended for vascular amputees. Only 4 are available for non-ambulatory individuals: AMPnoPro, TFP, OLBT and BAMS.


## Introduction

Peripheral arterial disease (PAD), with or without diabetes, is the main cause of amputation in high-income countries [1]. PAD often progresses into chronic limb-threatening ischaemia (CLTI), causing severe pain at rest or at night, ulceration and tissue loss [2]. It also frequently results in a deterioration in mobility and may ultimately require major lower-limb amputation.

'Vascular amputees' is here used to describe people who have undergone a major lower-limb amputation due to PAD and/or diabetes [3]. They often do not use a functional, weight-bearing prosthesis or ambulate following amputation [3]. Contemporary data suggest that only 40–45% of vascular amputees who attend prosthetic rehabilitation sessions are successfully fitted with a prosthetic limb. Additionally, up to 10% of these people abandon their prosthesis within 1 year [4].

Reasons for not being fitted with a functional prosthesis include: having multiple co-morbidities, level of amputation, baseline pre-amputation level of mobility, wound problems [5], potential problems on the contralateral lower limb [6], degree of frailty, and engagement with rehabilitation programmes [7].

Measuring physical performance with performance-based outcome measures (PerBOMs) is essential to identify a vascular amputee with a high, moderate or low physical performance ability. This facilitates frailty assessment, treatment and rehabilitation planning and can influence a successful outcome with a prosthetic limb [8]. Using PerBOMs also supports goal-setting, and focuses on functional activities of daily living; people who have had a vascular amputation often have a shorter life expectancy, greater frailty and multi-morbidities [9].

PerBOMs for those who have had an amputation due to PAD vary widely [10]. It is not clear which PerBOMs for vascular amputees are the highest quality or most appropriate to use in clinical practice [11]. In order to determine the quality of a physical performance measure it is necessary to evaluate their measurement properties, also known as clinimetrics [12,13]. To date, previous systematic reviews of outcome measures for amputees have not reported separate results for people who have undergone an amputation due to PAD and/or diabetes [14]; they have also grouped and compared several outcome measures together within the systematic review, including subjective patient reported outcome measures (PROM) and clinician reported outcome measures (CROM) with PerBOMs [15].

This systematic review presents the following research question: Which PerBOMs have adequate clinimetric properties to be recommended for use with those who have had an amputation due to PAD or diabetes?

This systematic review aims to explore which physical performance outcome measures are available for the assessment of physical performance or function in individuals following amputation due to PAD or diabetes prior to, during, or following an intervention, such as supervised exercise therapy or rehabilitation. Additional aims are to report and compare the measurement properties of these physical performance outcome measures to determine which are the highest quality and therefore provide recommendations as to which are the most appropriate to use within clinical practice and research.

## Methods

This systematic review was conducted following COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) [16,17] methodology for conducting systematic reviews for measurement properties for outcome measures and Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines [18]. The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42019160388).

### *Search strategy*

The search strategy was developed by the main author (AEA) and an experienced clinical librarian (CP). Searches were performed in MEDLINE, CINAHL, EMBASE, EMCARE, Cochrane Library, and Cochrane Central Register of Controlled Trials (CENTRAL) and Scopus from inception to October 2019. A full search strategy can be found in Supplementary Material A1. Searches were re-run in December 2020, June 2021, January 2022 and November 2022; no additional papers were included.

### *Inclusion criteria*

Abstracts and full-text articles were screened using inclusion and exclusion criteria (Supplementary Material A2). Studies evaluating the quality of an objective physical performance or functional outcome measure used with those vascular amputees were eligible for inclusion. Vascular amputees were defined as "individuals undergoing major lower-limb amputation (proximal to the ankle joint) due to PAD or diabetic foot disease". Preliminary searches revealed very few studies reporting data for this group of people exclusively. Therefore, we decided that studies which included vascular amputees, but reported aggregated data for a mixed cohort of amputation aetiologies (eg, trauma) would also be eligible.

Studies were included if they stated explicitly the assessment of measurement properties (reliability, validity, and responsiveness) of PerBOMs for the assessment of physical performance or functional ability, including objective measures of upper limb, lower limb and overall functional tasks to be completed pre- or post-amputation. Studies that were not in English, case reports and conference abstracts with insufficient data were excluded.

### *Study quality assessment*

The COSMIN methodology flowchart [17,25] was completed by 2 reviewers (AEA and either ED, JH, or AN) for each study. The risk of bias for each study was assessed using the COSMIN Risk of Bias checklist. Overall quality for each PerBOM was assessed using good measurement properties (Table 1). A modified GRADE (Grading of Recommendations, Assessment, Development and Evaluations) framework [16,25,26] was completed to provide a list of recommended PerBOMs.

### *Data synthesis*

Data for each PerBOM were presented in tables and a narrative synthesis of results undertaken. Included studies were categorised by PerBOM type and level of participant mobility. A meta-analysis was neither possible nor appropriate due to the heterogeneity of study designs, methodologies and PerBOMs investigated. COSMIN

**Table 1**
Definitions of clinimetric properties and data extracted from studies included in a systematic review of publications about objective physical performance-based outcome measures (PerBOMs) for the management of vascular amputees.

| Clinimetric property | Definition | Data extracted | COSMIN Good measurement properties criteria |
|---|---|---|---|
| Construct Validity | Construct validity is defined as the extent to which the outcome measure tests the hypothesis of what they aim to measure [19]<br>Convergent validity, a component of construct validity has been calculated for most studies, however these have been reported as construct validity in this review | Other comparator outcome measures, statistical testing with Spearman rank (R) or Pearson correlation co-efficient (p-value) | Sufficient (+):<br>Hypothesis in concordance with results of the study<br>Indeterminate (?):<br>No hypothesis has been defined by the study<br>Insufficient (-):<br>Results of the study are not in accordance with hypothesis |
| Predictive validity | The ability for the PerBOM to predict clinical variables, which is a component of criterion validity [13]. Comparator PerBOM should be collected after the time point of baseline PerBOM measure<br>Criterion validity is the ability for a test score to predict real life outcomes [20].<br>Concurrent validity, also a form of criterion validity is where all comparator data is collected at the same time point [21]. | Independent and dependant variables, method of regression analysis, area under the curve (AUC) or $R^2$ value | Sufficient (+):<br>Regression analysis data that has calculated an AUC of >0.70<br>Indeterminate score (?):<br>Not all data for the sufficient (+) rating was met<br>Insufficient rating (-):<br>The correlation with gold standard was <0.70 or AUC is <0.70 |
| Responsiveness | The ability for a PerBOM to measure changes accurately over time or performed in different situations [22]. | Sensitivity, specificity, and cut-off scores or MCID (Minimally Clinically Important Difference) | Sufficient (+):<br>In accordance with the hypothesis being tested or AUC >0.70<br>Indeterminate (?):<br>No hypothesis defined within the study<br>Insufficient (-):<br>Results are either not in accordance with hypothesis or AUC <0.70 |
| Reliability | The degree of repeatability and consistency in the measurement of a PerBOM [23].<br>Reliability has been categorised in this systematic review into internal consistency, test-retest reliability, inter-rater reliability and intra-rater reliability. | As described in the below 3 rows | Sufficient (+):<br>ICC or Cronbach Alpha value of >0.70<br>Indeterminate (?):<br>If an ICC or Cronbach Alpha was not reported<br>Insufficient (-):<br>ICC or Cronbach Alpha <0.70 |
| Test-retest reliability | The ability to obtain the same results from a stable population at different time points [23] | Intra Class Correlation co-efficient (ICC) | |
| Intra-rater reliability | Degree of similarity of scores of the same PerBOM between two individuals (raters) [23] | | |
| Inter-rater reliability | Repeatability of a PerBOM for the same rater [23] | | |
| Internal consistency | Degree to which the PerBOM individual items accurately measures the same characteristics [24] | Cronbach Alpha | |

The COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) good measurement properties checklist evaluates the methodological quality of study data for measurement properties and classifies them as sufficient (+), indeterminate (?), or insufficient (-). For references, see text.

guidelines [16,25,27] also recommend a narrative synthesis of results for systematic reviews of measurement properties.

## Results

Following screening, 48 full-text articles were included for data extraction and narrative synthesis. Screening and selection results are detailed in the PRISMA flow diagram (Fig. 1).

### *Study design*

Forty-eight articles were included reporting data from a total of 2651 individuals [15,28-74]: 20 were cross-sectional studies, 21 were prospective cohort studies, 3 were retrospective cohort studies, 1 was a longitudinal cohort study and 1 was a quasi-experimental study. Of these studies, 36 investigated validity [15,28-30,36,39,41-44,46,47,49-51,53-56,58-60,62-75], 20 investigated predictive validity [15,37-39,41,43,44,50,54-56,59,60,62,63,65,67,72,75], 22 investigated reliability or internal consistency [15,28,31,35,36,45,46,48-50,52,53,57,58,61,64,68,70-73,75]; and 7 investigated responsiveness (sensitivity and specificity) [29,38,39,42,44,56,67].

### *Cause of amputation*

The aetiology of amputation was heterogenous: the majority of studies investigated mixed-aetiology cohorts, including amputations due to trauma, malignancy, infection, congenital deformity and 'other', or unspecified, reasons in addition to vascular amputees. Of the 48 studies, 7 exclusively included vascular amputees [33,40,47,63,65,73,75] and 2 had mixed cohorts but reported results for vascular amputees separately [43,55]. Study cohort sizes were between 5 and 201 participants, and 14–100% of cohorts were vascular amputees. Overall, 1349/2651 participants included in this systematic review were vascular amputees (51%). Full details of all studies are described in Supplementary Material A3.

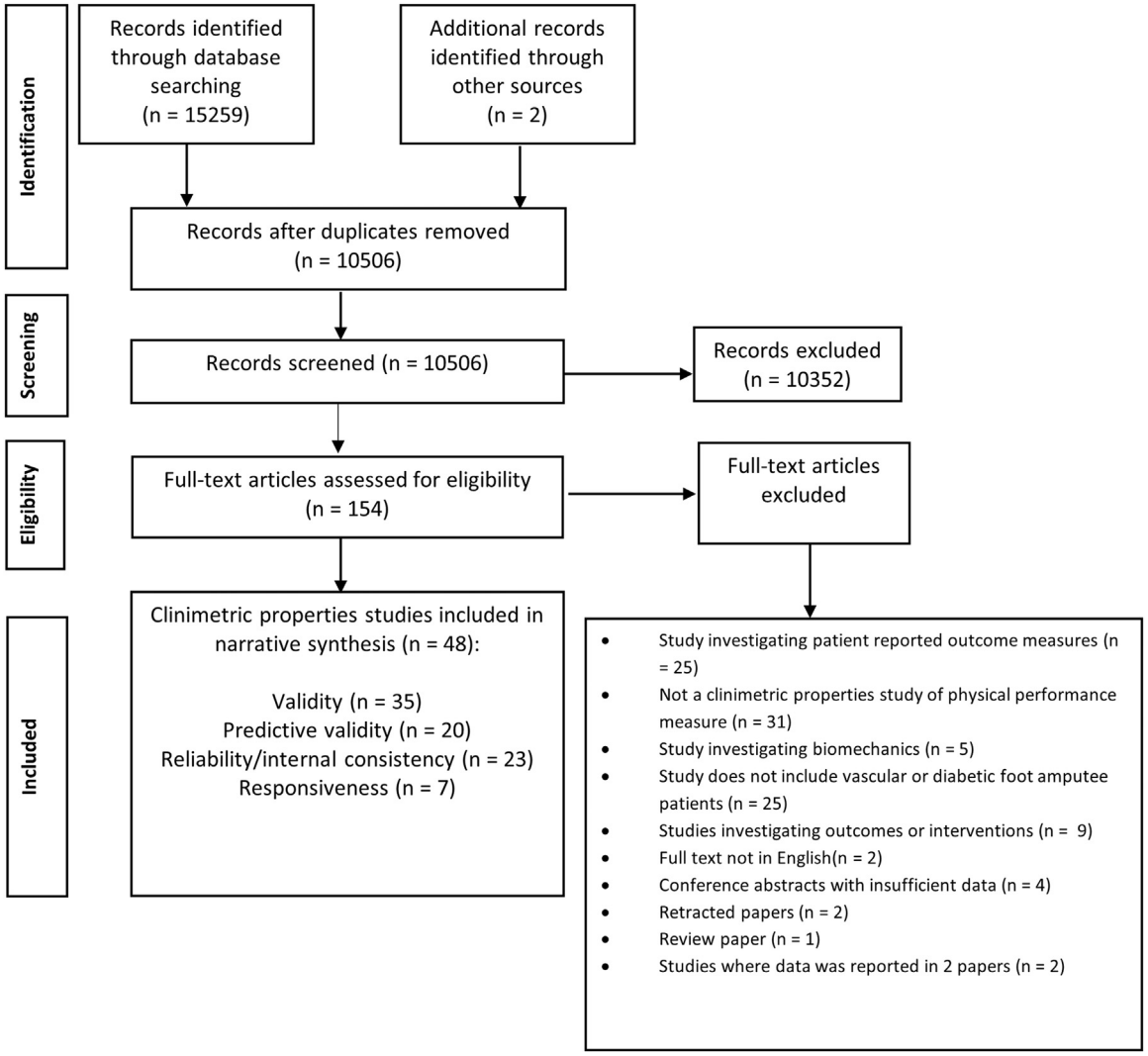


**Fig. 1.** PRISMA flowchart showing the number of included and excluded studies at each stage of the systematic review process into objective physical performance-based outcome measures (PerBOMs) for the management of vascular amputees.

*Physical performance-based outcome measures*

Overall, 34 PerBOMs were identified as having had a clinimetric component investigated by at least 1 study (Table 2). The Amputee Mobility Predictor no Prosthesis (AMPnoPro) [72], Basic Amputee Mobility Score (BAMS) [75], One-Leg Balance Test (OLBT) [37,46,56,64] and Transfemoral Fitting Predictor (TFP) [15] were all reported to be suitable for evaluating non-ambulatory people. Ambulation was reported as essential in 20 other PerBOMs that assessed balance, function and walking ability (Table 2). Five PerBOMs required digital equipment, such as digital gait assessment tools, accelerometers, and pedometers.

*Construct validity*

Convergent validity, a component of construct validity, was the methodological approach for validation of 22 PerBOMs (Table 3). The TFP was the only measure that reported discriminant validity alone [15]. Additionally, 3 of the 4 digital pedometers and accelerometers described assessed percentage accuracy for validation. The BBS (Berg Balance Scale) [30,44,50,56] was investigated by 4 studies (the largest number) and was compared to the Timed Up and Go Test (TUGT), 6-Minute Walk Test (6MWT), L Test, 2-Minute Walk Test (2MWT), Functional Reach Test (FRT), OLBT and Tandem test: the R (correlation coefficient) ranged between 0.35–0.85 and p-values were reported at <0.01–0.0001. The 6MWT was evaluated in 3 studies and was compared to TUGT, hip range of movement, and grip strength [43,59,64]: the R ranged between 0.54–0.95 and the p-values ranged between <0.0001–0.05. Two studies investigated 2MWT [56,60], TUGT [56,73] and OLBT [56,64]. All other PerBOMs were investigated only once each. An evaluation of an activity monitor for use with prostheses used the smallest cohort ($n$ = 12) [66].

*Predictive validity*

Predictive validity was used in studies of 18 PerBOMs [15,37-39,41,43,44,50,54-56,59,60,62,63,65,67,72,75] (Supplementary Material A4) to predict factors including successful future prosthesis use or walking [15,39,55,56,65,72], K-levels [37,43], 30-day mortality risk [75], risk of falling [50] and ability to perform other ambulatory PerBOMs [37,41,54,59,60,63,65]. The follow-up time for studies varied between 6 weeks and 2 years. Statistical analysis methods varied; they included regression analysis by linear, logistic and multivariate regression, calculations of Area Under the Curve (AUC) or $R^2$ value. Heterogenous and unclear statistical analyses were also found in some studies; they restricted meaningful comparisons using these data (Supplementary Material A4).

**Table 2**
Full list of physical performance-based outcome measures (PerBOMs) analysed in a systematic review of publications about their use for the management of vascular amputees.

| Type of PerBOM | Physical performance measure | Abbreviation | Upper Limb function | Mobility | Balance | Function | Predict Prosthetic use | Studies | Referecnce | Study Population amputation aeitology | Total participants (n) | Proportion of vascular amputees in the cohort, n (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Non-ambulatory | **Amputee Mobility Predictor no Prosthesis** | **AMP no Pro** | | | | | □ | 2 | [56,59] | PAD, T, M, C | 249 | 128 (51) |
| | **Basic Amputee Mobility Score** | **BAMS** | | | | □ | | 1 | [75] | PAD, DM | 106 | DM= 41 (39) |
| | **One Leg Balance Test** | **OLBT** | | | □ | | □ | 4 | [27,43,49,59] | PAD, T, I, O, M, C | 192 | 130 (68) |
| | **Transfemoral Fitting Predictor** | **TFP** | | | | | □ | 1 | [17] | PAD, PAD + DM, O | 93 | 76 (82) |
| Ambulatory | **2-Minute Walk Test** | **2MWT** | | □ | | | □ | 4 | [33,43,46,59] | PAD, T, I, M, C, O | 278 | 135 (49) |
| | **6-Minute Walk Test** | **6MWT** | | □ | | | □ | 4 | [30,45,49] | PAD, I, T,M | 286 | 61 (21) |
| | **10-metre Walk Test** | **10MWT** | | □ | | | □ | 2 | [30,58] | PAD, I, T,M, O | 254 | 80 (32) |
| | **180-Degree Turn Test** | **Turn180** | | | □ | | □ | 1 | [51] | PAD, DM, O | 47 | 32 (68) |
| | **Amputee Mobility Predictor** | **AMP Pro** | | | | | □ | 1 | [56] | PAD, T, M, C | 167 | 76 (46) |
| | **Berg Balance Scale** | **BBS** | | | □ | | □ | 8 | [24,26,36-38,43,67,68] | PAD, DM, M, T, O, DV, I, C | 230 | 111 (48) |
| | **Energy Cost of Walking** | **ECW** | | □ | | | □ | 1 | [48] | PAD | 24 | 24 (100) |
| | **Figure-of-8 Walk Test** | **F8W** | | □ | | | □ | 1 | [25] | M, T, I, C, PAD, O | 50 | 7 (14) |
| | **Four Square Step Test** | **FSST** | | | □ | | □ | 3 | [24,30,51] | T, PAD, M,I, DM,O | 288 | 76 (26) |
| | **Functional Reach Test** | **FRT** | | | □ | | □ | 1 | [43] | PAD, T, I, M, C | 64 | 42 (66) |
| | **Gait Deviation Index** | **GDI** | | □ | | | □ | 1 | [31] | PAD, I, T, M | 20 | 3 (15) |
| | **Lower extremity motor co-ordination test** | **LEMCOT** | | □ | □ | | □ | 1 | [59] | PAD, O | 82 | 52 (63) |
| | **L Test** | **L Test** | | □ | | | | 3 | [32,52,62] | PAD, O, T | 186 | 76 (41) |
| | **Narrow-Beam Walk Test** | **NBWT** | | □ | □ | | | 2 | [24,70] | T, DV, M, I | 40 | 7 (18) |
| | **Prosthetic Use for Mobility Outcomes tool** | **PUMP** | | | | | □ | 1 | [60] | PAD, DM, T, O | 40 | 28 (70) |
| | **Rivermead Mobility Index** | **RMI** | | | □ | □ | | 2 | [54,55] | PAD, T, M, I | 365 | 123 (34) |
| | **Sensory Organisation Test-** | **SOT** | | | □ | | | 1 | [39,65] | PAD, T | 15 | 7 (47) |
| | **Step Quick Turn Test** | **SQT** | | | □ | | | 1 | [44] | DM, PAD, T | 15 | 7 (47) |
| | **Tandem Test** | **Tandem Test** | | | □ | | □ | 1 | [43] | PAD, T, I, M, C | 64 | 42 (66) |
| | **Timed Up and Go** | **TUGT** | | □ | | □ | □ | 9 | [24,30,41-43,51,57,59,68] | PAD, M, T, O, DM, I, C | 580 | 282 (49) |
| Digital | **Arm Ergometer** | **A Ergometer** | □ | | | | □ | 2 | [35] | PAD | 101 | 101 (100) |
| | **Arm Leg Ergometer** | **A-L Ergometer** | □ | | | | □ | 1 | [34,61] | PAD, T, M, P, NF | 84 | 65 (77) |
| | **F Scan Sensor for gait assessment** | **F Scan Sensor** | | □ | | | | 1 | [64] | PAD, DM, T, M | 36 | 10 (28) |
| | **Hip/waist pedometer**<br>**Patient Activity Monitor**<br>**Yamax Digi-Walker pedometer**<br>**Modux Trex monitor** | **Accelerometers & Pedometers** | | | | | | 5 | [29,50,53,63,69] | PAD | 122 | 58 (48) |
| | **One Leg Cycle Test** | **1-L ergometer** | | | | □ | | 1 | [40] | PAD, T | 36 | 10 (28) |
| | **VO2 Maximum%** | **%VO2 Max** | | | | | □ | 1 | [47] | PAD, O | 64 | 23 (36) |

For the purposes of describing physical performance measures, PerBOMs were grouped into 'non-ambulatory', 'ambulatory', and 'digital'; The list of studies included aetiology of amputation, total number of participants, total number of vascular participants and percentage of vascular patients for individual PerBOMs; □, yes this variable was measured; Study population amputation aeitology abbreviations: C, Congenital; DM, Diabetes mellitus; DV, Dysvascular; I, Infection; M, Malignancy/Cancer; n, number; NF, Neurofibromatosis; O, Other/Unspecified; P, Pain; PAD, Peripheral arterial disease; Ref, References; T, Trauma; For references, see text.

**Table 3**
Construct validity reported for studies into objective physical performance-based outcome measures (PerBOMs) for the management of vascular amputees.

| Type of PerBOM | PerBOM | Author | n | n of vascular amputees in study (%) | CROM | Test | R | p-value | R Range | COSMIN rating | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Non-ambulatory | **Amputee Mobility Predictor no Prosthesis** | Gailey 2002 [72] | 167 | 76 (46) | 6MWT | S | 0.69 | <0.001 | 0.69 | V | + |
| | **Basic Amputee Mobility Score** | Kristensen 2018 [75] | 100 | 100 (100) | ** | x2 test | *** | <0.001 | *** | A | + |
| | **One-Leg Balance Test** | Gremeaux 2012 [56] | 64 | 42 (66) | BBS, FRT, OLBT, Tandem test, 2MWT, TUGT | PC | 0.35 to 0.8 | <0.01−0.0003 | 0.35−0.80 | A | + |
| | | Lin 2008 [64] | 13 | 4 (31) | TUGT | PC | 0.61 to 0.63 | <0.05 | | A | + |
| | **Transfemoral Fitting Predictor** | Condie 2011 [15] | 93 | PAD= 53 (57) PAD+DM=23 (25) | ** | | *** | *** | *** | D | ? |
| Ambulatory | **2-Minute Walk Test** | Gremeaux 2012 [56] | 64 | 42 (66) | BBS, FRT, OLBT, Tandem test, 2MWT, TUGT | PC | 0.35−0.8 | <0.01−0.0005 | 0.35 to 0.80 | A | ? |
| | | Parker 2010 [60] | 46 | 20 (39) | SAM | S | SAM= 0.45 to 0.78 | SAM= 0.000−0.02 | | A | + |
| | **6-Minute Walk Test** | Reid 2015 [43] | 86 | 21 (24) | 2MWT, TUGT | PC | 2MWT: 0.95 TUG= −0.72 | <0.0001 | 0.54−0.95 | A | + |
| | | Lin 2008 [64] | 13 | 4 (31) | TUGT | PC | 0.76 | <0.05 | | A | + |
| | | Raya 2010 [59] | 72 | 20 (28) | Hip extension, abduction, plantarflexion, grip strength | PC | 0.54 to 0.69 | <0.0001 | | V | + |
| | **10-metre Walk Test** | Datta 1996 [74] | 53 | 43 (81) | *Barthel, FAI, Volpicelli | C | Barthel= −0.29 FAI= −0.34 Volpicelli= −0.31 | <0.05 | 0.29−0.31 | I | - |
| | **Amputee Mobility Predictor Prosthesis** | Gailey 2002 [72] | 167 | 76 (46) | 6MWT | S | 0.82 | <0.001 | 0.82 | V | + |
| | **Berg Balance Scale** | Azuma 2019 [30] | 30 | 3 (10) | TUGT, 6MWT | S | TUGT= −0.85 6MWT= −0.82 | <0.001 | 0.35−0.85 | V | ? |
| | | Wong 2014 [44] | 46 | 32 (70) | ** | S | 0.73 | *** | | V | + |
| | | Major 2013 [50] | 30 | 7 (23) | L test, 2MWT | S | 2MWT= 0.68 L test= −0.080 | <0.001 | | V | + |
| | | Gremeaux 2012 [56] | 64 | 42 (66) | BBS, FRT, OLBT, Tandem test, 2MWT, TUGT | PC | 0.35 to 0.80 | <0.01−0.0001 | | V | + |
| | **Energy Cost of Walking** | Traballesi 2008 [63] | 24 | 24 (100) | Treadmill and floor walking test | BP | 0.74 | <0.001 | 0.74 | A | ? |
| | **Figure-of-8 Walk test** | Schack 2019 [28] | 50 | 7 (14) | AMP, 10MWT, 6MWT | T | *** | AMP=0.04 10MWT=0 0.38 6MWT=0.78 | *** | V | + |
| | **Functional Reach Test** | Gremeaux 2012 [56] | 64 | 42 (66) | BBS, FRT, OLBT, Tandem test, 2MWT, TUGT | PC | 0.35 to 0.8 | <0.01−0.0002 | 0.35−0.80 | A | + |
| | **L Test** | Deathe 2005 [68] | 93 | 37 (40) | TUG, 10MWT, 2MWT | PC | TUGT=0.93 2MWT= −0.86 10MWT=0.97 | <0.001 | 0.86−0.097 | A | + |
| | **Rivermead Mobility Index** | Franchignoni 2003 [71] | 140 | 74 (53) | 10MWT | S | TWT= 0.7 | <0.0001 | 0.70 | V | + |
| | **Sensory Organisation Test** | Jayakaran 2013 [51] | 15 | 7 (15) | AP-COP | S | 0.39−0.97 | none calculated | 0.39−0.97 | A | + |
| | **Step Quick Turn Test** | Jayakaran 2011 [58] | 15 | 7 (47) | TUGT | S | AL: TT/TS=0.52 to 0.89 UL: TS=0.35 to 0.85 | AL: TT= <0.001 TS= <0.05−0.001 UL: TT/TS= <0.05−0.001 | 0.58−0.75 | V | + |
| | **Timed Up and Go Test** | Gremeaux 2012 [56] | 64 | 42 (66) | BBS, FRT, OLBT, Tandem test, 2MWT, TUGT | PC | 0.35−0.80 | <0.01−0.0006 | 0.35−0.80 | V | + |
| | | Schoppen 1999 [73] | 32 | 32 (100) | *GARS, SIP68 | S | GARS=0.39 SIP68=0.46 to 0.36 | GARS=0.03 SIP68=not stated | | D | ? |
| | **Tandem test** | Gremeaux 2012 [56] | 64 | 42 (66) | BBS, FRT, OLBT, Tandem test, 2MWT, TUGT | PC | 0.35−0.80 | <0.01−0.0004 | 0.35−0.80 | A | ? |

(*continued on next page*)

**Table 3** (*Continued*)

| Type of PerBOM | PerBOM | Author | n | n of vascular amputees in study (%) | CROM | Test | R | p-value | R Range | COSMIN rating | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Digital | **Arm ergometry** | Erjavec 2008 [65] | 63 | 63 (100) | 6MWT | D* | 0.51 | <0.0001 | 0.51 | A | + |
| | **Hand wheel ergometer** | Erjavec 2014 [47] | 101 | 101 (100) | 6MWT (VO2 Max), HR | A* | *** | <0.001 | *** | A | + |
| | **Modus Trex Activity Monitor** | Godfrey 2018 [36] | 29 | 11 (38) | 6MWT, AMPPRO | C | AMPRO=0.93<br>6MWT=0.89 | <0.001 | 0.89–0.93 | V | ? |
| | **One leg cycle test** | Wezenburg 2012 [53] | 36 | 10 (28) | Age, BMI and sex | *** | *** | age=0.02<br>BMI<0.001<br>sex= 0.02 | *** | I | ? |
| | **Patient Activity Monitor** | Dudek 2008 [66] | 20 | 4 (20) | Step count (video) | *** | *** | 71–94% **** | *** | I | ? |
| | **Prosthetic Activity Monitor** | Bussman 2004 [69] | 12 | PAD=2 (17)<br>DM=2 (17) | Walking distance | *** | *** | 0.039–0.22<br>98–99% **** | *** | I | ? |
| | **VO2 Max (%)** | Hammamura 2009 [62] | 64 | 23 (36) | Stand on one leg | F | *** | <0.05 | ? | I | - |
| | **Yamax Digi Walker** | Dudek 2008 [66] | 20 | 4 (20) | Step count (video) | *** | *** | 75–94% **** | *** | I | ? |

* Patient-reported outcomes measures (PROM) only reported; ** Discriminant validity investigated; *** not stated; ****=% accuracy, (+) sufficient, (-) insufficient, (?) indeterminate; 10MWT, 10-metre Walk Test; 2MWT, 2-Minute Walk Test; 6MWT, 6-Minute Walk Test; A*, ANOVA; A, adequate; AL, Amputated Limb; AP-COP, Anterior-Posterior Centre Of Pressure; AMP, Amputee Mobility Predictor; BBS, Berg Balance Scale; BMI, Body Mass Index; BP, Bravais-Pearson correlation; C, Correlation coefficient; COSMIN, COnsensus-based Standards for the selection of health Measurement INstruments; CROM, Clinically Reported Outcome Measure; D, doubtful; D*, Discriminant analysis; DM, Diabetes mellitus; F, Fishers exact test; FAI, Frenchay Activities Index; FRT, Functional Reach Test; GARS, Groningen Activity Restriction Scale; HR, Heart Rate; I, inadequate; n, Number; OLBT, One Leg Balance Test; PAD, Peripheral Arterial Disease; PC, Pearson's correlation; p, p-value; PerBOM, Performance-based outcome measures; R, Spearman or Pearson rank correlation coefficient; RMI, Rivermead Mobility Index; SAM, Step activity monitor; SIP, Sickness Index Profile; S, Spearman rank correlations; T, Student's T-test; TT, Turn Time; TS, Turn Sway; TUGT, Timed Up and Go; Turn180, 180-Degree Turn Test; UL, Unaffected Limb; V, very good. For references, see text.

PerBOMs with sufficient ability to predict future walking ability included the TUGT [39,54-56], AMPnoPro [37,72], OLBT [37,56], Lower extremity motor co-ordination test (LEMCOT) [37], 6MWT [39,59], 2MWT [43,56,60], 10-metre Walk Test (10MWT) [39], BBS [44,50,56], Four Square Step Test (FSST) [39,67], FRT [56], and PUMP tool [38]. Although the TFP [15], BAMS [75], AMPnoPro [72] and OLBT [39,59] measures predict future prosthesis use, they do not include tasks that require ambulation, and so can be completed by a non-ambulatory person.

*Responsiveness*

Seven studies investigated sensitivity and specificity (Table 4). The PerBOMs evaluated were the Narrow-Beam Walking Test (NBWT) [29], TUGT [29,39,67], FSST [29,39,67], BBS [29,44], PUMP tool [38], 10MWT [39], 6MWT [39], L Test [42], 2MWT [56], and the 180-Degree Turn Test (Turn180) [67]. Risk of bias COSMIN ratings for all except 3 PerBOMs [67] were reported to be very good. The NBWT [29], TUGT [29], FSST [29], BBS [29], and Turn180 [67] PerBOMs identify participants who are likely to fall, using reported cut-off scores. The TUGT [39], FSST [39], 10MWT [39], 6MWT [39] and PUMP tool [38] were all used to predict successful prosthetic use at 12 months; the AUC ranged between 0.743–0.788. The highest AUC reported in any study, 0.958, was reported when the PUMP tool was used to predict successful prosthesis use 12 months post-discharge [38]. The only study to produce a minimally clinically important difference (MCID) value for clinical use was the L test [42]. However, this is currently classified as insufficient for use, due to an AUC <0.70.

*Reliability*

Twenty-two studies [15,28,31,34-36,45,46,48-50,52,53,57,58,61,64,68,70-73] investigated either reliability and/or internal consistency for 23 PerBOMs (Table 5). Test-retest reliability and inter-rater reliability are reported separately to reflect the exact measurement property that was investigated within studies. Internal consistency was measured in the BBS [49,50], Rivermead Mobility Index (RMI) [71], OLBT [46], Figure-of-8 Walk Test (F8W) [28] and TFP [15] tools. Each of these PerBOMs, except RMI, were scored as very good on the COSMIN Risk of Bias checklist, and were classed as sufficient on the good measurement properties scale. The RMI [71] was classified as doubtful on the COSMIN risk of bias checklist, with an indeterminate good measurement properties score. Test-retest reliability, assessed in 13 PerBOMs, was the most commonly reported sub-category of reliability used to assess PerBOM quality.

*Summary of results*

A summary of findings of each PerBOM, categorised by their pooled effect of measurement properties and GRADE ratings, are described in Table 6.

*Non-ambulatory measures*

Only 4 PerBOMs were identified as suitable and appropriate for use with vascular amputees who were also non-ambulatory: AMPnoPro [72], BAMS [34,75], TFP [15] and OLBT [56,64]. The AMPnoPro [72] is a high-quality measure, with adequate construct validity and inter-rater and test re-test reliability.The AMPnoPro [72] and TFP [15] were only investigated by 1 study each. The BAMS [75] is an assessment of basic transfers and is suitable for someone early post-amputation: it was one of the few PerBOMs tested only with people with amputations due to vascular disease. The BAMS had sufficiently good measurement properties for construct validity and reliability, but a prediction of 30-day mortality risk for participants with a BAMS score <2 demonstrated insufficient measurement properties [75].

**Table 4**
Responsiveness table describing values for sensitivity and specificity of performance-based outcome measures (PerBOMs) from a systematic review of publications about the use of PerBOMs for the management of vascular amputees.

| Type of PerBOM | PerBOM | Author | Study End-point | Sensitivity % (CI) | Specificity % (CI) | Positive likelihood ratio | Negative likelihood ratio | Area under ROC curve (CI) | Cut-off score | COSMIN | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Ambulatory | **2-Minute Walk Test** | Gremeaux 2012 [56] | 2 | 93–47 | 71–94 | 50–70% * | 97–85% ** | 0.93 (0.83–0.97) | 130.00–15.00 m | V | + |
| | **6-Minute Walk Test** | Roffman 2016 [39] | 3 | 81 (64–92) | 72 (64–78) | **** | **** | 0.79 (0.72–0.84) | <191.00 m | V | + |
| | **10-metre Walk Test** | Roffman 2016 [39] | 3 | 67 (49–81) | 76 (68–82) | **** | **** | 0.74 (0.68–0.80) | <0.44 m/s | V | + |
| | **Berg Balance Scale** | Wong 2014 [44] | 2 | 82 | 75 | 3.27 | **** | 0.83 (0.72–0.95) | **** | V | + |
| | | Sawers 2019 [29] | 1 | 67(48–86) | 62 (9–86) | 1.80 (0.89–3.6) | 0.53 (0.27–1.10) | 0.66 (0.47–0.83) | 50.50/56.00 | V | - |
| | **Four Square Step test** | Roffman 2016 [39] | 3 | 81 (64–92) | 71 (64–78) | **** | **** | 0.76 (0.69- 0.82) | >36.60 s | V | + |
| | | Dite 2007 [67] | 1 | 92 | 93 | 86% * | 96% ** | | ≥24.00 s | A | + |
| | | Sawers 2019 [29] | 1 | 74(58–92) | 68 (46–92) | 2.40 (1.10–5.2) | 0.36 (0.17–0.78) | 0.70 (0.53–0.86) | 8.49 s | V | + |
| | **L Test** | Rushton 2015 [42] | 4, 5 | 0.5 | 0.43 | **** | **** | 0.67 | 4.50 s *** | V | - |
| | **Narrow-Beam Walking Test** | Sawers 2019 [29] | 1 | 83(68–98) | 76 (54–96) | 3.00 (1.50–6.9) | 0.24 (0.13–0.56) | 0.81 (0.6- 0.91) | 0.43 | V | + |
| | **PUMP tool** | Wong 2016 [38] | 3 | 100–63 | 96–67 | 14.9–1.00 | 0.14–0.39 | 0.958 | | V | + |
| | **Timed Up and Go Test** | Dite 2007 [67] | 1 | 85 | 74 | 61%* | 91%** | **** | ≥19.00 s | A | + |
| | | Roffman 2016 [39] | 3 | 75 (58–88) | 78.3 (71- 85) | **** | **** | 0.80 (0.73–0.85) | >21.40 s | V | + |
| | | Sawers 2019 [29] | 1 | 83(68–98) | 68 (46–92) | 2.60 (1.30–5.6) | 0.24 (0.13–0.56) | 0.71 (0.54–0.88) | 8.17 s | V | + |
| | **Turn-180°** | Dite 2007 [67] | 1 | 100–31 | 78–85 | 50–65%* | 72–100%** | **** | TT: ≥3.70 s<br>TS: ≥6 steps | A | + |

Confidence intervals for Sensitivity, Specificity and Area Under the ROC Curve have been included in table where studies have reported this data; 1 Establish cut-off scores for people who fall; 2, Predict successful prosthetic mobility/function; 3, Predict prosthesis use 12 months post-discharge; 4, MCID; 5, Responsiveness; 6, discriminating patients likely to fall; *, positive predictive value; **, negative predictive value; ***, MCID, Minimally clinically indicated difference; ****, not reported; COSMIN, COnsensus-based Standards for the selection of health Measurement INstruments; COSMIN result, (+) sufficient, (-) insufficient, (?) indeterminate; A, adequate; D, doubtful; I, inadequate; m, metres; m/s, metres per second; *sec*, seconds; TT, Turn Time; TS, Turn Steps; V, very good.

**Table 5**
Reliability and internal consistency table of studies into objective physical performance-based outcome measures (PerBOMs) for the management of vascular amputees.

| Type of PerBOM | PerBOM | Author Year | n | n of vascular amputees in study (%) | Reliability | Internal consistency | Chronbach's Alpha | Test re-test reliability | ICC | Inter-rater reliability | ICC | Intra rater reliability | ICC | COSMIN | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Non-ambulatory** | **Amputee Mobility Predictor no Prosthesis** | Gailey 2002 [72] | 167 | 76 (46) | □ | | | □ | 0.86–0.97 | □ | 0.99 | | | V | + |
| | **Basic Amputee Mobility Score** | Kristensen 2018 [75] | 30 | 19 (63) | □ | | | | | □ | 0.98 | | | V | + |
| | **One leg balance test** | Kristensen 2014 [46] | 36 | 17 (47) | □ | □ | *** | | | □ | 0.87 | | | V | + |
| | | Lin 2008 [64] | 13 | 4(31) | □ | | | □ | UL=0.93–0.70 AL= 0.48- 0.40 | | | | | V | - |
| | **Transfemoral Fitting Predictor** | Condie 2011 [15] | 93 | 53 (57) | □ | □ | 0.92 Il=0.55–0.84 | | | □ | 0.99–0.91 | | | V | + |
| **Ambulatory** | **6-Minute Walk Test** | Lin 2008 [64] | 13 | 4(31) | □ | | | □ | 0.94 | | | | | V | - |
| | **Amputee Mobility Predictor Prosthesis** | Gailey 2002 [72] | 167 | 76 (46) | □ | | | □ | 0.96–0.98 | □ | 0.99 | | | V | + |
| | **Berg Balance Scale** | Wong 2014 [45] | 5 | 2 (50) | □ | | | | | □ | 0.99 | □ | 0.99 | V | + |
| | | Major 2013 [50] | 30 | 7 (23) | □ | □ | 0.83 | | | □ | 0.95 | | | A | + |
| | | Wong 2013 [49] | 40 | 15 (38) | | RR | PSI= 0.88 ISI= 0.96 | | | | | | | V | + |
| | **Dual Task L test** | Hunter 2018 [35] | 60 | 20 (33) | □ | | | □ | 0.98 (0.94;0.99) | | | | | A | + |
| | **Figure-of-8 Walk test** | Schack 2019 [28] | 50 | 7 (14) | | □ | 0.99–0.88 | | | | | | | V | + |
| | **Gaitrite system** | Corio 2010 [61] | 34 | 4 (12) | □ | | | □ | 0.98–0.88 * | | | | | A | ? |
| | **L test** | Deathe 2005 [68] | 93 | 37 (40) | □ | | | | | □ | 0.96 | □ | 0.97 | V | + |
| | **Rivermead Mobility Index** | Ryall 2003 [70] | R: 73 IC: 225 | R:18 (25) IC:49(22) | □ | | | □ | ICC= 0.99 KC = 1.00–0.70 | | | □ | ICC=0.90 KC= 1.0–0.78 | A | + |
| | | Franchignoni 2003 [71] | 140 | 74(53) | | □ | 0.85 | | | | | | | D | ? |
| | **Single Task L Test** | Hunter 2018 [35] | 60 | 20 (33) | □ | | | □ | 0.97 (0.87;0.99) | | | | | A | + |
| | **Sensory Organisation Test** | Jayakaran 2011 [57] | 15 | 3 (20) | □ | | | □ | 0.94- 0.26 | | | | | A | + |
| | **Step Quick Turn test** | Jayakaran 2011 [58] | 15 | 7 (47) | □ | | | □ | 0.85–0.95 | | | | | A | + |
| | **Timed Up and Go Test** | Schoppen 1999 [73] | 32 | 32 (100) | □ | | | | | □ | 0.96 ** | □ | 0.96 ** | A | + |

(*continued on next page*)

**Table 5** (*Continued*)

| Type of PerBOM | PerBOM | Author Year | n | n of vascular amputees in study (%) | Reliability | Internal consistency | Chronbach's Alpha | Test re-test reliability | ICC | Inter-rater reliability | ICC | Intra rater reliability | ICC | COSMIN | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Digital** | **Cruiser arm-leg ergometer** | Simmelink 2018 [31] | 21 | 2 (12) | □ | | | | | | | □ | VO2=0.84 HR=0.68 PO=0.91 | A | + |
| | **F scan sensor** | Agrawal 2013 [52] | 5 | 2 (40) | □ | | | □ | 0.89 | | | | | D | + |
| | **Modus Trex Activity Monitor** | Godfrey 2018 [36] | 29 | 11 (38) | □ | | | □ | 0.92–0.87 | | | | | A | + |
| | **One-legged cycle test** | Wezenberg 2012 [53] | 36 | 10 (28) | □ | | | □ | 0.89 | | | | | V | + |
| | **Pedometers** | | | | | | | | | | | | | | |
| | **SW-701** | Briseno 2014 [48] | 39 | 17 (44) | □ | | | | | □ | 0.15 | | | A | - |
| | **NL-800** | | | | | | | | | | 0.55 | | | | - |
| | **Omron** | | | | | | | | | | 0.97 | | | | + |

*Pearson Product Moment correlation co-efficient; **, Spearman Correlation Co-efficient; **, *Not stated; □ yes this variable was measured; (+) sufficient, (-) insufficient, (?) indeterminate; A, adequate; AL, Amputated leg; COSMIN, COnsensus-based Standards for the selection of health Measurement INstruments; D, doubtful; HR, Heart rate; I, Inadequate; IC Internal consistency; ICC, Intraclass Correlation Coefficient; II, Individual items; ISI, Item Separation Index; CK Cohen's Kappa; PerBOM, Performance-based outcome measure; PO, Peak power output; PSI, Pearson Separation Index; R Reliability; RR, Rach rating; UL, Unaffected Leg; VO2, $VO_2$ Max.

The TFP [15] included the largest population of vascular amputees from all non-ambulatory measures ($n$ = 93). Construct validity and predictive validity for TFP had inadequate measurement properties due to limited reported data. Reliability was adequate, with high ICC scores for inter-rater reliability and high internal consistency. The TFP overall modified GRADE rating was moderate. The OLBT [56,64] requires a person to stand on 1 leg for a set time; it demonstrated adequate construct validity, adequate inter-rater reliability and predictive validity.

### *Upper limb tests*

For evaluation of upper limb physical performance, only 2 PerBOMs were identified within the literature: the arm-leg ergometer [31] and the arm ergometer [47,65]. Both evaluate upper limb performance and have also been validated in relation to cardio-pulmonary function and prediction of successful prosthesis use. There is low-to-moderate evidence for either ergometer being useful for the latter purposes. Both the arm [47,65] and arm-leg ergometer [31], showed only adequate reliability when used with a vascular amputee population; therefore neither PerBOM would be recommended.

### *Predicting prosthesis use*

Types of regression analysis reported include logistic regression, linear regression, multivariate regression and AUC. Ambulatory PerBOMs that predict success with a prosthetic limb in the longer term, or predict higher functional abilities with a prosthesis, were also evaluated: participants must use their prosthetic limb functionally and be able to ambulate independently. According to the COSMIN risk of bias and GRADE ratings there was high quality evidence to support the use of the AMPnoAmPro [72], TUGT [39,54-56], PUMP tool [38], LEMCOT [37], 10MWT [39], 2MWT [43,56,60] and 6MWT [39,59] PerBOMs.

### *Balance and predicting future falls*

BBS is the most extensively assessed, balance-based PerBOM currently for use with vascular amputees; it was assessed in 8 studies. The BBS [44,50,56] is used to assess balance ability, fall frequency and successful ambulation with a prosthesis. Results indicated it was found to be high quality with sufficient good measurement properties for construct validity, reliability, responsiveness and predictive validity. Moderate quality evidence, with sufficient measurement properties, was demonstrated for the FSST [39,67].

### *Timed walking tests*

The TUGT [29,33,37,39,55,56,67,73] clinimetric properties were investigated by 8 studies. Results, both individual and pooled, demonstrated sufficient evidence for predictive validity, responsiveness, and reliability. The COSMIN risk of bias assessment indicated that the construct validity level of evidence was indeterminate. The TUGT has also been used as a comparator PerBOM for studying convergent validity (Table 2).

Both the 2MWT and 6MWT have sufficient evidence for construct validity, predictive validity and responsiveness. However, the 6MWT was classed as having insufficient evidence for reliability. The 2MWT has not had reliability investigated in any study; it is therefore difficult to rank these 2 timed walking tests any differently.

There were insufficient data to evaluate the Energy Cost of Walking (ECW) [63] and the Gait Deviation Index (GDI) [41] measures with ambulatory vascular amputees; neither would be recommended for clinical use.

**Table 6**
Summary of findings table describing overall good measurement properties rating and modified GRADE(Grading of Recommendations, Assessment, Development, and Evaluation) for studies into objective physical performance-based outcome measures (PerBOMs) for the management of vascular amputees.

| | PerBOM | Construct validity | Predictive validity | Responsiveness | Reliability | GRADE |
|---|---|---|---|---|---|---|
| Non Ambulatory PerBOM | Amputee Mobility Predictor no Prosthesis | + | + | | + | High |
| | Basic Amputee Mobility Score | + | ? | | + | Moderate |
| | One Leg Balance Test | + | + | | – | Moderate |
| | Transfemoral Fitting Predictor | – | – | | + | Moderate |
| Ambulatory PerBOM | 2 Min Walk Test | + | + | + | | High |
| | 6 Min Walk Test | + | + | + | – | High |
| | 10 metre Walk Test | – | + | + | | High |
| | 180 Degree Turn Test | | | + | | High |
| | Amputee Mobility Predictor | + | | | + | High |
| | Berg Balance Scale | + | + | + | + | High |
| | Energy Cost of Walking | ? | – | | + | Low |
| | Figure of 8 Walk Test | + | | | + | High |
| | Four Square Step Test | | + | + | | Moderate |
| | Functional Reach Test | + | + | | | Moderate |
| | Gait Deviation Index | | – | | | Very low |
| | L Test | + | | – | + | Moderate |
| | Lower extremity motor co-ordination test | | + | | | Moderate |
| | Narrow Beam Walk Test | | | + | | High |
| | Prosthetic Use for Mobility Outcomes tool | | + | + | | High |
| | Rivermead Mobility Index | + | | | ? | Moderate |
| | Sensory Organisation Test | + | | | + | Moderate |
| | Step Quick Turn Test | + | | | + | High |
| | Tandem Test | ? | – | | | Low |
| | Timed Up and Go | ? | + | + | + | High |
| Ergometer | Arm Leg Ergometer | ? | | | | Low |
| | Arm Ergometer | + | – | | + | Moderate |
| | One Leg Cycle Test | ? | | | | Very low |
| | VO2 Maximum (%) | – | – | | | Very low |
| Digital PerBOM | F Scan Sensor for gait assessment | ? | | | + | Very Low |
| | Gaitrite system | ? | | | ? | Very Low |
| | Hip/waist pedometer | ? | | | | Very low |
| | Modus Trex Activity Monitor | | | | + | Moderate |
| | Prosthetic Activity Monitor | ? | | | | Very low |
| | Pedometers: Yamax Digi-Walker, SW-701, NL-800, Omron | ? | | | – | Very low |

Summary of findings table describing overall clinimetrics of each PerBOM; for the purposes of describing physical performance measures, PerBOMs were grouped into 'non-ambulatory', 'ambulatory', and 'digital'; the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) good measurement properties checklist evaluates the methodological quality of study data for measurement properties and classifies them as sufficient (+), indeterminate (?), or insufficient (-); modified GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) has been reported as per COSMIN guidelines and classifies PerBOMs by overall quality, Very low, Low, Moderate, High.

*Mixed measures*

Mixed measures that assess walking ability and balance ability in one test are combined in the F8W [28] and NBWT [29,32]. The F8W [28] is a walking test with turns (walking in a figure-of-8 pattern). The NBWT [29,32], a walking test along a straight beam that decreases in width, reflecting real-life situations with the incorporation of turns when walking. Our analyses indicated that the F8W has sufficient evidence for construct validity and to predict successful prosthesis use, as well as having a high GRADE rating; sufficient as a measure for balance assessment in an ambulatory vascular amputee wearing a prosthesis in the long-term. However, the F8W [28] would also be suitable as a dual-purpose PerBOM, to predict the success of prosthesis use and to monitor progression, therefore it seems to be a superior PerBOM.

*Digital perboms*

Digital gait assessment of physical performance is possible with an F-scan sensor [52] and the Gaitrite system [61]. Both demonstrated very low-quality evidence; we would not recommend them for either research purposes or clinical gait assessment. Yamax Digi Walker accelerometers [66], and the Patient Activity Monitor (PAM) [66] all had an accuracy of up to 94% when compared to observed step counts. However, all accelerometers and pedometers included in this systematic review were scored as indeterminate for construct validity. We found the Modus Trex Activity Monitor [36] accelerometer to have the best measurement properties and sufficient data to predict future walking success for people with a prosthesis who had an amputation due to vascular disease.

## Discussion

This systematic review identified a huge number of PerBOMs that assess different aspects of physical performance in vascular amputees including ambulation, cardiopulmonary function, functional walking ability, turning and balance. Some PERBOMs also assess several aspects of physical performance. The vast majority of PerBOMs investigated require patients to be ambulatory and assess walking ability or predict future prosthesis use. Study methodologies varied and included assessment of ≥1 PerBOM or clinimetric properties in each study.

*Study cohorts*

Data are limited; this area is hugely under-researched for those who may be classified as a vascular amputee. Most studies included those with amputations following vascular disease as a minority, within a mixed cohort of participants. We found that the general reporting of amputation aetiology, especially amongst vascular amputees, was poor: only 7/48 studies included vascular disease exclusively as the sole amputation aetiology while 2 (other) papers presented results for vascular aetiology separately to other amputation groups.

Studies investigating ambulatory PerBOMs included fewer people who had amputations due to vascular disease than non-ambulatory PerBOM studies. Conversely, non-ambulatory PerBOM study

populations had a greater percentage of people whose amputations had a vascular aetiology. This is probably because of the limited numbers of vascular amputees who are ambulatory in the community [76].

### *Suitability*

We found PerBOMs to be an effective tool in assisting with setting holistic SMART (specific, measurable, attainable, realistic, and timed) goals. However, of the 34 PerBOMs, investigated in this systematic review only 2 (OLBT and BAMS) can be used to set attainable and realistic goals for the majority of people who have had an amputation due to vascular disease, as they are often older, frail, non-ambulatory and do not aim to walk with a prosthesis. Conversely, the other 2 non-ambulatory PerBOMs (AMPnoPro and TFP), are only suitable for predicting future success with prosthesis use. This makes them relevant only for people whose goal is to walk with a prosthesis; something that is unrealistic for many vascular amputees.

Floor and ceiling effects were not reported specifically or statistically analysed in this systematic review owing to a lack of available data within the studies. However, there are evident floor effects in ambulatory PerBOMs, which would result in non-ambulatory people with amputations being unable to complete any tasks. Furthermore, even the highest quality non-ambulatory PerBOM, the OLBT, has clear floor effects: someone with bilateral amputation would be unable to complete this test. The BAMS is one of the only PerBOMs to have a reported ceiling and floor effect. However, the ceiling effect is large, indicating that it would be poor at discriminating amongst amputees with high physical performance.

### *Clinical utility*

Clinical utility, feasibility and acceptability of identified PerBOMs was not reported explicitly within the included studies. PerBOMs are required at different times throughout a person's healthcare journey; something reflected in the wide range of PerBOMs identified by this systematic review. Dual-use, or mixed-measure, PerBOMs may prove to be more clinically acceptable if PerBOMs to assess global function could be used at different points to assess, or predict, physical performance. For non-ambulatory PerBOMs, the OLBT has dual use as a non-ambulatory measure, as well as having predictive ability. However, owing to the evident limitations of the non-ambulatory PerBOMs and their variable quality, it highlights a need for a new mixed measure that is suitable for the non-ambulatory vascular amputee.

In clinical practice, predicting successful functional prosthesis use and walking is important for early identification of people that require prosthesis rehabilitation, and those who do not. This enables resources to be directed to those who will most benefit from prosthesis rehabilitation [77]. Conversely, inaccurate identification may prevent individuals from receiving the rehabilitation they require and could affect the quality of care provided to people with vascular amputations. Therefore, future research should focus on predictive PerBOMs for those with amputations who are non-ambulatory to assist with streamlining appropriate treatments and services to the correct people.

Digital PerBOMs present an opportunity for modernisation and accurate assessment of physical performance within current clinical practice. However, the included studies have not explored the cost of equipment, their practicality, nor acceptability of the new digital PerBOMs. Importantly, these could be deciding factors for amputees undergoing rehabilitation when using these devices in clinical practice.

**Table 7**
Table of recommended physical performance-based outcome measures (PerBOMs) for the management of vascular amputees.

| | |
|---|---|
| **Non-Ambulatory** | Amputee Mobility Predictor no Prosthesis |
| | One Leg Balance Test |
| **Upper Limb** | none |
| **Timed walking** | 2 Min Walk Test |
| | 6 Min Walk Test |
| | 10 metre Walk Test |
| | L test |
| | Timed Up Go Test* |
| **Predicting prosthetic use** | 2 Min Walk Test |
| | 6 Min Walk Test |
| | 10 metre Walk Test |
| | Amputee Mobility Predictor Prosthesis |
| | Lower Extremity Motor Co-ordination Test |
| | Prosthetic Use for Mobility Outcomes tool |
| | Timed Up and Go Test |
| **Balance** | Turn 180° test |
| | Berg Balance Scale |
| **Mixed measure** | Figure of 8 Test |
| | Narrow Beam Walking Test |
| **Digital** | Modus Trex Activity Monitor |

List of PerBOMs produced based on previous research investigating the clinimetrics of PerBOMs for patients who have undergone an amputation due to vascular disease; for the purposes of describing physical performance measures by clinical use, PerBOMs were grouped into 'non-ambulatory','upper limb', 'timed walking', 'predicting prosthetic use', 'balance', 'mixed measure' and 'digital'; *, gold standard test.

### *Recommendations*

Based on the results, a list of recommended PerBOMs for vascular amputees, as defined above, has been produced (Table 7). The OLBT has a dual use: assessing overall physical performance and predicting prosthesis use and is recommended as the best non-ambulatory PerBOM studied. We would also recommend the AMPnoPro for clinical use with non-ambulatory amputees, it is rated as a high-quality PerBOM.

Due to the heterogeneity of methods used for investigating predictive validity and various endpoints, it is difficult to compare and synthesise data and recommend a superior PerBOM with predictive validity for use with vascular amputees. Therefore, a list of high-quality, predictive PerBOMs has been provided (Table 7).

The TUGT is the only walking test assessed for all aspects of clinimetric properties. It is recommended as a gold standard for use in clinical practice and future research. Other timed walking tests that demonstrated high-quality evidence and recommended for clinical use are the 2MWT, 10MWT, and 6MWT and the BBS. The only digital PerBOM to be suggested for clinical use with vascular amputees is the Modus Trex Activity Monitor accelerometer.

### *Strengths and limitations*

This systematic review is the first to investigate all available PerBOMs with vascular amputees and to evaluate their quality using clinimetrics specific to this population. This review also covers all clinimetric measurement properties, including construct validity, predictive validity, internal consistency, inter-rater and intra-rater reliability and responsiveness of PerBOMs. Previous research [14] has included all types of outcome measures, including CROMs, PROMs and PerBOMs. These measures are all developed and evaluated with different methods, and they measure very different aspects of health experience and physical function. Thus, they are incomparable.

Methodologies reported in studies in this systematic review varied hugely, with diverse, and sometimes ambiguous, reporting of clinimetric properties. Some studies intermingled terms for PROMs, instead of clinimetric terms for PerBOMs. Additionally, methods for statistical data analysis were often inconsistent, especially for

predictive validity. Therefore, a meta-analysis of data was impossible. Few studies included exclusively vascular amputees, and many had only a small number of vascular amputees in their cohort. Whilst the decision to include them was made to provide breadth to the review, it does reduce the reliability of conclusions specific to a vascular amputee cohort. Additionally, descriptions of cohort aetiology were poor; vascular amputees are a diverse population, and young people undergoing amputation for diabetic foot disease are likely to have different outcomes than older people with gangrene due to CLTI. This study considered vascular amputees all together because in the literature they are frequently reported as a single cohort, but this also limits the generalisability of the findings to all vascular amputees. Thus, due to these factors, synthesis of data for vascular amputees alone was impossible.

Other limitations of this systematic review are the use of COSMIN methodology for systematic reviews of PerBOM measurement properties, as this methodology and guidelines were originally formulated for PROM studies. However the COSMIN handbook provides advice, which was followed, for using this methodology for systematic reviews of PerBOMs/clinimetric studies [25,26]. It was difficult to assess how commonly individual PerBOMs included in this review are used in clinical practice. Future research should focus on exploring if the identified PerBOMs within the literature are being used pragmatically within clinical practice and also if they are useful to clinicians.

## Conclusion

A list of recommended PerBOMs for vascular amputees has been produced in this systematic review. As highlighted, the majority of PerBOMs identified are for amputees who are ambulatory, and are thus inappropriate for use with people who have an amputation due to vascular disease, since they are often non-ambulatory. Existing PerBOMs for non-ambulatory amputees have limited evidence and applicability in clinical practice. An alternative, comprehensive, PerBOM tool is required to facilitate assessment and treatment of people who have had an amputation due to vascular disease throughout their healthcare journey.

## Declaration of Competing Interest

None

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