The Future of Outcome Measurement: Developing a Strategic List of Prosthetic Outcome Measures for a Smart Device Application (app)

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Research Project

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Developing a Strategic List of Prosthetic Outcome Measures for a Smart Device Application (app)

Abstract

Background: As the field of prosthetics and orthotics continues to advance, the need to validate the effectiveness of patient treatment plans is paramount.[1] Despite the availability of numerous outcome measures (OMs),[4] several barriers limit their use in clinical practice including: lack of time, resources, and practitioner knowledge. We propose the development of a prosthetic outcome measure smart-device application (app) to help reduce the barriers of routine outcome measurement. **Purpose**: The purpose of this research project is twofold: to compile an updated list of OMs suitable for prosthetic practice to minimize the barrier of appropriate outcome measure selection and to create a strategic list of OMs most appropriate for use in clinical practice at Atlantic Prosthetics Inc. (API), which includes measures of four important constructs of the prosthetic experience: mobility, function, quality of life, and patient satisfaction. **Methods:** A search of relevant literature was conducted. An updated list of outcome measures that evaluate important constructs suitable for use by prosthetists was compiled. The primary list of suitable outcome measures was further evaluated for strategic selection of outcome measures to be included in the app. **Results:** An updated list of 28 OMs suitable for use by prosthetists was compiled and deemed the "primary list" (Table 1). 8 OMs met the population, construct, and psychometric criteria and were selected for the app. **Conclusions:** The PEQ-MS[8,18,8], 6MWT[8,5], TAPES-R[8] , AMPPRO[8,25,5] PCI[19], PLUS-M™,[18,20]ABC Scale[18], and OPUS-HRQOL©[5] were found to be the most reliable, valid, and appropriate for evaluating function, mobility, quality of life, or satisfaction in persons with lower limb amputation. 5 OMs will be utilized in the initial app to be piloted at API.

Background

As the field of prosthetics and orthotics continues to advance, the need to validate the effectiveness of patient treatment plans is paramount.[1] The goals of prosthetic treatment are to improve functionality and quality of life among individuals with limb loss. These goals require outcome measures (OMs) specifically designed to quantify them.[2] This means practitioners must assess outcomes related to body structure and function, activity level and ability to carry out tasks, participation in life situations, and overall quality of life.[3] Despite the availability of numerous OMs to assess these qualities,[4] several barriers limit their use in clinical practice. These barriers include lack of time, resources, and practitioner knowledge to select and implement appropriate outcome measures.

The first challenge for practitioners is finding and interpreting research to select appropriate OMs for specific patients[5]. It is critical to select quality OMs, which have strong validity and reliability for the particular population of interest[4]. Furthermore, the best OMs are responsive and precise enough to measure change over time, acceptable for the patient of interest, feasible for the clinical situation, and interpretable for the practitioner to apply the result to clinical decision-making (A. Richardson, personal communication, February 12, 2015). Many practitioners lack the skills and experience to find and interpret OM research[5].

Lack of time is a commonly reported barrier for using OMs. Even for a practitioner who is experienced at locating and analyzing OMs, selecting the appropriate one for a given clinical scenario is a time consuming process. In addition, finding time to actually implement the OM into practice is challenging[6]. Ease of administration will further impact the feasibility of an OM[5]. OMs that require a lot of set up, costly materials, and large spaces may not be feasible for every clinic. It is hypothesized that the additional work of documenting OM scores and manually entering scores into electronic health records (EHRs) may further inhibit the adoption of regular outcome measurement.

Recently, applications (apps) have been developed and utilized for individual outcome measures to combat some of these barriers. For example, in 2013 an iPAD app version of the DASH Outcome Measure was released, providing real-time administration, scoring and tracking of results over time[7]. The app made it more efficient for clinicians to use DASH and interpret its results[7]. To date, no app exists which contains more than one prosthetic OM in a single app, and directly links to pre-existing EHR software. We propose the development of a prosthetic

outcome measure smart-device application (app) to help reduce the barriers of routine outcome measurement. Hypothesized benefits of an OM app for the practitioner include: easy access to the best available OMs, the ability to quickly select the most appropriate OM for any clinical scenario, facilitate simple measurement of the OM on the app, and directly export the results into the patient's electronic health record (EHR) on pre-existing EHR software.

Project Introduction

The first steps in developing the prosthetic OM app are the research and pilot phases. To ensure the best available OMs are included in the app, a review of relevant literature must be completed. Several recent review studies have evaluated outcome measures available for use with individuals with amputations. In 2014, Heinemann and colleagues provided an update on currently available outcome instruments suitable for prosthetic practice.[8] Their review provides findings from previous reviews[4,9] and a subsequent search of literature extending up to 2013. Heinemann's review selected 24 outcome measures "that measure constructs suitable for use by prosthetists."[8]

Following the selection of best available outcome measures, a pilot version of the app will be created to test it in the clinical setting. A private prosthetic facility, Atlantic Prosthetics Inc., will be the first facility to pilot the app; therefore OM selection for the app will be strategically geared toward OMs appropriate for its patient population and clinical resources. The purpose of this research project is twofold:

> **Part 1:** To compile an updated list of OMs suitable for prosthetic practice to minimize the barrier of appropriate outcome measure selection.
>
> **Part 2:** To create a strategic list of OMs most appropriate for use in clinical practice at Atlantic Prosthetics Inc. (API), which includes measures of four important constructs of the prosthetic experience: mobility, function, quality of life, and patient satisfaction.

For readability, the methodology and results of Part 1 are discussed consecutively, followed by the methodology and results of Part 2. This research will contribute to the overarching goal of developing an outcome measurement, data collection, and data reporting application (app) to be used with numerous smart-devices.

Part 1: Primary List of Suitable Prosthetic Outcome Measures

Methods

Literature-Review

A search of relevant literature was conducted. The search method mimicked that of the search strategy outlined by Condie and colleagues[4] in the Medline database and Wright[9] in the Pubmed database. Dates were restricted from 2014-current to capture only articles more recent than the previous Heinemann review[8]. Articles were included if they proposed a new outcome instrument not evaluated by Heinemann[8] or provided further evaluation of an existing outcome instrument, adding to the insight into that instrument's performance. Only articles written in English were included. Additional information about OMs was obtained by hand searching the references cited in these articles, and the references cited in previous reviews.

Primary list of Suitable Prosthetic Outcome Measures

An updated list of outcome measures that evaluate important constructs suitable for use by prosthetists was compiled. For this review, important constructs considered suitable for use by prosthetists included: mobility, function, quality of life, and patient satisfaction. An OM was selected for the list if 1) it was previously included on Heinemann's (2014) list[8]; or 2) recent literature sufficiently supports its validity, reliability, and sensitivity to change. An OM was excluded if it did not measure mobility, function, quality of life, or patient satisfaction in individuals with amputations. This list is subsequently referred to as the "primary list".

Results

Literature Review

The primary literature search identified 9 articles, which provided further insight into OMs previously evaluated, or introduced new OMs not discussed in previous reviews. These 9 articles are presented in the reference list #10 - 18. From the primary literature search, 10 unique OMs were found. Of these 10 OMs, 4 met the outlined criteria for inclusion and were added to the updated primary list of prosthetic outcome measures.

Primary list of Suitable Prosthetic Outcome Measures

An updated list of 28 outcome measures suitable for use by prosthetists was compiled and deemed the "primary list" (Table 1). OMs #24-28 are summarized detail below. Please refer to Heinemann's review for parallel summaries of OMs #1-24[8].

Table 1. ***Primary List of Suitable Outcome Measures***

#	Abbreviation	Outcome Measure
Heinemann (2014) Recommended		
1	10MWT	10 Meter Walk Test
2	ABC Scale	Activities-Specific Balance Confidence Scale
3	AMPPRO	Amputee Mobility Predictor
4	ACMC	Assessment of Capacity for Myoelectric Control
5	AM-ULA	Activities Measure for Upper Limb Amputees
6	BBS	Berg Balance Scale
7	BBT	Box and Block Test
8	JTHF	Jebsen-Taylor Test of Hand Function
9	LCI	Locomotor Capabilities Index
10	L-Test	L-Test of Functional Mobility
11	OPUS-LEFS	Orthotics and Prosthetics Users' Survey Lower Extremity Functional Status
12	OPUS-UEFS	Orthotics and Prosthetics Users' Survey Upper Extremity Functional Status
13	PSFS	Patient-Specific Functional Scale
14	PEQ-MS	Prosthesis Evaluation Questionnaire Mobility Scale
15	PPA	Prosthetic Profile of the Amputee
16	PUFI	Prosthetic Upper Extremity Functional Index
17	6MWT	6 minute walk test
18	TUG	Timed Up and Go.
19	TAPES-R	Trinity Amputation and Prosthesis Experience Scales—Revised
20	2MWT	2 minute walk test
21	OPUS-HRQOL©	Orthotics and Prosthetics Users' Survey Health-Related Quality of Life
22	PROMIS	Patient-Reported Outcome Measurement Information System
23	SCS	Socket Comfort Score;
24	OPUS -	Orthotics and Prosthetics Users' Survey Satisfaction

	Satisfaction	
Literature Review Support		
25	QuickDASH	Shortened - Disabilities of Arm, Shoulder, and Hand
26	UNB	University of New Brunswick (UNB) Test
27	PCI	Physiological Cost Index
28	PLUS-M™	The Prosthetic Limb Users Survey of Mobility

The Shortened - Disabilities of Arm, Shoulder, and Hand (QUICKDASH) is an 11-item self-report disability questionnaire.[15] Respondents rank their perceived difficulty performing activities, perceived limitations, and the extent of interference with activities on a 5-point linkert scale.[15] Scores from all items are summed and averaged; the value is transformed to a score from 0 to 100 by subtracting 1 from the average and multiplying by 25. A higher score indicates greater disability.[15]

Recent literature supports the use of the QuickDASH for individuals with upper extremity amputation in clinical practice.[15] Researchers reported good internal consistency (Cronbach's alpha = 0.83), test-retest reliability (ICC= 0.87) and validity in a sample of 44 upper limb amputees.[15] Convergent validity was found with several validated OMs including PSFS, OPUS-UEFS, and TAPES. Minimum detectable change reported at the 95% confidence level (MDC95%) was 17.4.[15]

The University of New Brunswick (UNB) Test is a performance measure for individuals with upper limb amputation. It involves 10 tasks, which are typical daily tasks based on the age of the participant. Administrators present the activities and observe spontaneous performance, without providing instructions regarding the use of the prosthesis. Each activity is typically performed using two hands and is rated on spontaneous use of the prosthesis and on skill of prosthetic use using a dual rating scale.[16]

UNB has been previously recommended for use with children. A recent study of 45 adults with upper extremity amputation demonstrated acceptable internal consistency (Cronbach's alpha of 0.74-0.75 for the spontaneity scale and 0.69-0.79 for skill), reliability (test-retest ICC=0.74 - 0.79), and showed preliminary evidence of validity for use with adults.[16] MDC95% was estimated as 0.8 points for spontaneity scale and 0.9 points for the skill scale.[16]

"The Physiological Cost Index (PCI) is a clinical measurement used to estimate the energy cost of walking".[19] PCI is an inexpensive and less cumbersome estimate of energy cost compared to gold standard of direct oxygen uptake (VO2) measurement.[19] The test involves having the patient walk on even ground for 5 minutes. To obtain the PCI value, the mean heart rate (HR) at rest and the mean HR of the last 3 minutes of walking (to ensure steady state) is calculated. Walking distance is divided by time to give the walking speed in m/min. Change in HR is divided by walking speed. The resultant PCI value describes the number of extra heartbeats required per meter walked.[19]

A study of 28 (non-dysvascular) adults with unilateral lower limb (trans-tibial or higher) amputation demonstrated strong test-retest reliability (ICC=0.966) and construct validity of the PCI.[19] The study provides known-group scores for adults with a unilateral lower-limb amputation due to reasons other than vascular disease, and for healthy adults.[19] Smallest detectable change (SDC) was found to be 0.116 for adults with amputation and 0.07 in healthy adults.[19]

The Prosthetic Limb Users Survey of Mobility™ (PLUS-M™**)** "is a self-report instrument for measuring mobility of adults with lower limb amputation. It has been rigorously developed using modern psychometric methodology and is intended for use in clinical practice and research."[20] Two short forms exist which require only 2-3 minutes to administer. A patient's T-score is compared to the original PLUS-M™ development sample of 1091 unilateral lower limb prosthesis users. A T-score of 50 represents the mean mobility reported by the development sample population.[20]

Recent literature supports the reliability (test-retest ICC=0.96) of PLUS-M™ for group studies as well as clinical applications such as tracking individual patients over time[18]. Content and face validity are supported by its rigorous design process, utilizing previously validated measures such as the PROMIS. MDC90% is 4.50.[20]

Part 2: Strategic Selection of Prosthetic Outcome Measures

Methods

The primary list of suitable outcome measures was further evaluated for strategic selection of outcome measures to be included in the Prosthetic Outcome Measures smart-device application

(app). This refined list is subsequently referred to as the "strategic list". The selection process, detailed below, was based on the following criteria:

1. Each OM included must be applicable for primary patient population at API
2. The strategic list must include at least 1 OM for each important construct (mobility, function, quality of life, and patient satisfaction).
3. Psychometric Evaluation

Criteria 1 Selection: Population Study

To inform the selection of outcome measures applicable for the patient population at Atlantic Prosthetics Inc. (API), demographical information was obtained from API's electronic health record software, P&O Expert, in order to determine the primary patient population(s).

Based on the results of the population study, the initial list of OM was refined to include only OM suitable for the primary patient population at API. Outcome measure selection was directed toward OMs that are applicable for the individuals with lower extremity amputations; OMs exclusively applicable for individuals with upper-limb amputations were de-selected. OMs shown to be appropriate only for the adolescent and paediatric populations were also removed from the list.

Criteria 2 Selection: Important Constructs

To ensure a comprehensive measurement app, the completed list will include at least 1 OM that measures each of the important constructs relevant to prosthetic treatment. Therefore at minimum, the recommended list must include one mobility OM, one functional OM, one quality of life (QoL) OM, and one OM for patient satisfaction (PS).

An OM was considered to evaluate mobility if its tasks/questions included only those directly related to body movement (ie. walking, balancing). Any OM which included functional tasks/questions such as activities of daily living (ADLs) or activities with an object were considered functional OMs (ie. picking up an object).

Criteria 3 Selection: Psychometrics

Evidence for psychometric properties was established by cross-referencing review literature. If needed, further investigation into specific OM properties was done through an informal search of the literature. The following psychometric properties were investigated for each OM:

a. **Appropriateness**
b. **Reliability** (*Test-retest)*
c. **Validity** *(Content and Construct)*
d. **Responsiveness** (*Minimal Detectable Change*)

Deathe[21] previously defined these 4 properties in detail. [21] The rationale and criteria used to evaluate each psychometric property in this study is outlined below.

a. Appropriateness

OMs were considered appropriate if they were suitable for measurement of an individual patient within the clinical setting at API for the purpose of tracking change in a construct (function, mobility, quality of life, or satisfaction) over time or assessing change in a construct due to a prosthetic treatment intervention. OMs not considered appropriate for this specific purpose were excluded.

b. Reliability

Test-retest reliability, is an important factor in determining measures recommended for individual-level applications.[18] A minimum test-retest reliability intraclass correlation coefficient (ICC) of > 0.9 is recommended if an OM is to be used to evaluate ongoing treatment effects on an individual.[18] While, it is generally accepted that measures demonstrating test-retest reliability ICC > 0.70 are suitable for group comparisons.[18] OMs shown to have test-retest reliability ICC > 0.9 were recommended for app inclusion. To satisfy criteria #2, if no OMs of a specific construct (ie. Quality of Life) have a test-retest reliability ICC > 0.9, the OM with the highest test-retest reliability will be selected for inclusion. Inter-rater reliability was not considered in this strategic selection, because the same practitioner will be involved in all OM collection during the app pilot period.

c. Validity

Evidence of face and/ or content validity was provided by previous reviews [4,8] or through this study's literature review as a prerequisite for inclusion on the "primary list." Further evidence of each OMs construct validity is investigated.

d. Responsiveness

Minimal Detectable Change (MDC) and/or Minimal Clinically Important Difference (MCID) are measures of an OMs responsiveness. A reported MDC or MCID is required to determine if a change in OM score is due to a true change in construct or due to measurement variability. OMs

were excluded from the recommended list in the absence of published MDC or MCID values. Only 1 of MDC or MCID were required for inclusion.

Final Selection: Strategic List

Outcome measures that met criteria 1-3 were selected for the strategic list and recommended for inclusion in the prosthetic OM smart-device application.

Pilot Selection

Before completing full app development, a pilot period of one year will be completed to test app function and ease of use, and to troubleshoot any problems. Five OMs were selected for the pilot app. With the goal of comprehensively testing the app, a mixture of patient report and performance-based measures will be targeted.

Results

The following sections discuss the step-by-step results of strategic outcome measure selection for the Prosthetic Outcome Measures smart-device application (app) for Atlantic Prosthetics Inc. (API).

Round 1 Selection: Population Study

The patient demographics of Atlantic Prosthetics are presented below. Figure 1 compares the percentage of patients who have lower extremity amputations vs upper extremity amputations. Patient population age-demographics are shown in Figure 2. Notably, 83% of the patient population is lower extremity, and the significant majority (96%) is adult (21 years and older) and elderly (65 years +). Based on the results of the population study, the primary list of 28 was revised. 20 OMs remained for psychometric evaluation.

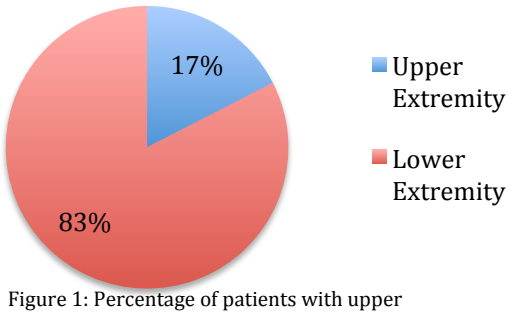

Figure 1: Percentage of patients with upper extremity vs. lower extrmity amputations at Atlantic Prsothetics Inc.

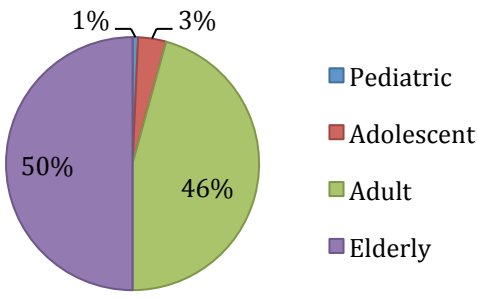

Figure 2: Patient Demographics by Patient Age at Atlantic Prosthetics Inc.

Criteria 2 Selection: Constructs

The 20 OMs that fulfilled criteria #1 were categorized based on the construct in which they measure (Table 2). 8 measure *mobility*, 7 measure *function*, 3 measure *quality of life* (QoL), and 2 measure *patient satisfaction* (PS).

Table 2. *Number of Outcome Measures Categorized by Construct*

Patient Satisfaction	2	Function	7
Mobility	8	Quality of Life	3

Criteria 3 Selection: Psychometrics

a. Appropriateness

Of the 20 remaining OMs, 19 were considered appropriate. One OM, the Prosthetic Profile of the Amputee (PPA) was not considered appropriate. The PPA was excluded from consideration as it is recommended only for research, not for individual clinical applications.[8]

b. Reliability

Of the remaining 19 OMs, 10 OMs had literature evidence of strong reliability (based on test-retest reliability). Five *mobility* OMs were found to have test-retest reliability ICC > 0.9 and were included. Three OMs of *function* were found to have test-retest reliability ICC > 0.9 and were included. No *quality of life* (QoL) or *patient satisfaction* (PS) OMs had test-retest reliability ICC > 0.9. To satisfy criteria #2, the OMs that had the strongest test-retest reliability within these categories was selected. The OPUS-HRQOL© had the strongest reliability of QoL measures and was included. TAPES-R had the strongest reliability of PS OMs and was included.

c. Validity

The validity (content, face, and construct) of the remaining 10 measures was found to be supported in literature. (ABC Scale,[8] BBS,[8] PEQ-MS,[8] L-test,[8] OPUS-HRQOL©,[8] 6MWT,[22] PCI,[19] TAPES-R,[23,24] PLUS-M™,[18,20] AMPPRO[22,25].)

d. Responsiveness

Eight OMs had MDC values available (PEQ-MS[8,18,8], 6MWT[8,5], TAPES-R[8], AMPPRO[8,25,5] PCI[19], PLUS-M™,[18,20] ABC Scale[18], OPUS-HRQOL©[5]). Two OMs (BBS, L-test) did not have MDC or MCID values reported in literature and were thus excluded.

Final Selection: Strategic List

Eight OMs met the population, construct, and psychometric criteria and were selected for the strategic list for inclusion in the prosthetic OM smart-device application. The strategic list included two OMs assessing function, four OMs assessing mobility, one assessing quality of life, and one OM assessing patient satisfaction. An overview of each selected OM, its method of application, and scoring system is provided in Table 3a. Table 3b outlines the psychometric data for each selected OM.

Table 3a. Strategic List of Prosthetic Outcome Measures for Smart-Device Application - Overview

OM	Name	Description	CON	MOA	Scoring
ABC Scale	Activities-Specific Balance Confidence Scale	16-item self-report measure of confidence in performing various ADLs without falling.[8]	AF	PR	Items rated from 0-100. Higher score represents higher balance confidence.[8]
*AMP	Amputee Mobility Predictor	21-task measure of ambulatory potential of people with lower limb amputations with (AMPPRO) and without a prosthesis (AMPnoPro). Evaluates transfers, sitting and standing balance, and gait skills.[8]	AF	P	Tasks are rated by the administrator based on the patient's performance of each task. The number of points available varies for each task (between 1-5 points). Maximum AMPPRO score is 47, 43 for AMPnoPRO.[22]
PEQ-MS	Prosthesis Evaluation Questionnaire Mobility Scale	13-item mobility scale measures ambulation and transfer ability. 9 items address walking mobility, and 4 items address transfer activities.[8] Items include: walking up and down stairs and hills, sitting down and getting up from a chair or toilet, and walking on various surfaces.[26]	AM	PR	Original scoring based on a 100-point visual analog scale (VAS). Miller et al scored using a numeric likert scale from 0-10. The total score is calculated as a mean all items.[26]

6MWT	6 minute walk test	Measures endurance over a set period as an indicator of functional mobility. Participants walk along a straight corridor for 6 minutes at a self-selected walking speed. Participants may use a mobility aid and rest if needed.[8]	AM	P	Score is recorded as the distance walked (in metres) during the 6-minute period.
*PLUS-M	Prosthetic Limb Users Survey of Mobility 12-item short form	Measures mobility of adults with lower limb amputation. There are 2 available short forms (PLUS-M 7, PLUS-M 12).[20] A computerized adaptive test (CAT) that selectively administers items from the PLUS-M™ item bank is also available on http://plus-m.org/cat.html[20]	AM	PR	PLUS-M™ instruments each yield a T-score that ranges from 17.5 to 76.6. The patient's T-score is compared to the known group values based on the original PLUS-M development sample of 1091 unilateral lower limb prosthesis users. A T-score of 50 represents the mean mobility reported by the development sample population.[20]
PCI	Physiological Cost Index	Clinical measure used to estimate the energy cost of walking. Patients walk on even ground for 5 minutes while wearing a heart rate monitor.[19]	AM	P	The mean heart rate (HR) at rest and the mean HR of the last 3 minutes of walking is calculated. Walking distance is divided by time to give the walking speed in m/min. Change in HR is divided by walking speed to obtain PCI value. The PCI value describes the number of extra heartbeats required per meter walked.[19]
*TAPES-R Patient satisfaction subscales will be utilized.	Trinity Amputation and Prosthesis Experience Scales—Revised	Multi-dimensional instrument to examine the psychosocial processes involved in adjusting to amputation and to a prosthesis. a) It contains 64-items across 6 subscales.[27] Subscales #5 (aesthetic) and #6 (functional) assess patient satisfaction. Subscales can be used	PS & QoL	PR	Items within each subscale are summed and then averaged. Scoring provides six individual subscale scores.[27] Detailed scoring information is provided in the TAPES-R guide available at: http://psychoprosthetics.ie/tapes-r [27]

		individually or the complete TAPES-R can be used to provide a comprehensive picture.[27]			
* OPUS-HRQOL	Orthotics and Prosthetics Users' Survey Health-Related Quality of Life	This module of the OPUS comprises 23 items assessing health related quality of life. Items include: "how often during the past week have you been happy?"; "how much does your physical condition restrict your ability to do chores? [28]	QoL	PR	Items are evaluated on a 5-point rating scale. The OPUS Health Quality of Life Score is the sum of the scores for the 23 items (0 – 92). A higher score indicates a better outcome.[29]

Abbreviations: OM, outcome measure abbreviation; CON, construct; MOA, mode of administration; AF, activity-function; AM, activity-mobility; PS, patient satisfaction; QoL, quality of life; PR, patient report; P, performance.

Table 3b. Strategic List of Prosthetic Outcome Measures for Smart-Device Application - Psychometrics

OM	Test-retest Reliability	Construct Validity	Responsiveness (MDC)
ABC Scale	ICC = 0.91[8] ICC=0.95[18]	Convergent with 2MWT & TUG[8]	MDC90=0.49[18]
* AMP Psychometric data reported for AMPPRO only.	ICC = 088[8] ICC=0.96-0.98[22]	Excellent validity in measuring functional capabilities.[25] Convergent Validity with: 6MWT & Amputee Activity Survey (AAS)[22]	MDC90 =3.3[25]-3.4[5,8]
PEQ-MS	ICC = 0.77[8] ICC=0.92[18] ICC= 0.85[5]	Convergent with: 2MWT, TUG, ABC, & LCI [8] Convergent with LCI[25]	MDC90 = 0.8[8] MDC90=0.55[18]
6MWT	ICC = 0.97[8]	Convergent with: AMPPRO[22]	MDC90=147.5[8] MDC90 = 45meters[5]
PLUS-M™	ICC=0.96[18]	Strong evidence of construct validity. Correlation with AMP, TUG, PEQ-MS, ABC.[30]	MDC90 = 4.50[18]
PCI	ICC = 0.966 and 0.948[19]	Positive relationship between PCI and a higher level of amputation supports the validity of the measurement among amputees.[19]	SDC = 0.116[19]
*TAPES-R Psychometric data reported only for satisfaction subscales	ICC = 0.86[8]	Construct Supported [23,24]	MDC90 = 0.79[8] MDC95 = 0.83[8]
*OPUS-HRQOL©	ICC = 0.85[5]	Construct Supported[8,28]	MDC90 = 9.2[5]

Abbreviations: OM, Outcome Measure abbreviation; MDC90, minimal detectible change at 90% confidence; MDC95, minimal detectible change at 95% confidence; SDC, smallest detectable change; ICC, intraclass correlation coefficient.

Pilot App

Five OMs were selected for use in the app pilot. OMs selected for the pilot list are denoted with an asterisk (*) in Table 3a and Table 3b. The pilot list selection included at least one OM from each construct, as well as, a mix of patient-report (PR) and performance (P) based modes of assessment.

Discussion

This review was completed to 1) compile an updated list of OMs suitable for prosthetic practice, to minimize the barrier of appropriate outcome measure selection; and to 2) create a strategic list of OMs most appropriate for use in clinical practice at Atlantic Prosthetics Inc. (API), which includes measures of four important constructs of the prosthetic experience: mobility, function, quality of life, and patient satisfaction.

Part 1 of this review added four new OMs to the comprehensive list of OMs supported for use in prosthetic clinical practice provided in Heinemann's 2014 review.[8] The QuickDASH and UNB are valuable OMs for measuring upper extremity functional[15, 16]. The PCI is an inexpensive and less cumbersome estimate of energy cost, more feasible for use in clinical practice than the gold standard VO2 testing[19]. PLUS-M™ is a rigorously developed self-report measure of mobility in adults with lower limb amputation.[20] These four measures had recent literature support for their psychometric strength and are important additions to a comprehensive list of OMs suitable for clinical practice[15,16,18,19,20].

This primary list of 28 contains OMs that have been validated for use with various patient populations and provides the starting point for further evaluation. From this primary list, strategic selection of OMs will vary per facility depending on their goals, patient population, and prioritized psychometric properties.

Part 2 of this review focused on selecting a strategic list to be utilized in development of a prosthetic outcome measure smart device application, to be piloted at API. Selection focused on OMs suitable for use with adults with lower extremity amputation. From the primary list of 28, 8 were selected for the "strategic list" and recommended for use in the OM app. These OMs were selected because they are the most appropriate for use with individual adult patients with lower extremity amputation for the purpose of tracking a change in a construct (function, mobility, quality of life, or satisfaction) over time or assessing change in a construct due to a

prosthetic treatment intervention. All OMs selected on the strategic list had excellent validity, had the highest test-retest reliability among OMs of each construct, and reported a minimal detectable change. This strategic list does not contain OMs specific for individuals with upper extremity amputation or for paediatric individuals with amputation.

Limitations

Several limitations must be placed on the research results. Firstly, the author is an inexperienced researcher, limiting the rigour of this review. Secondly, psychometric evaluation was based on 1) a review of current literature after 2014, 2) the psychometric values reported in previous reviews[4,8] and 3) by hand searching the references within previous reviews and the current literature. Despite attempts to be thorough, it is possible that psychometric data exists that was not found in this review. Specifically if psychometric data was published before 2014 but was not included in these previous reviews. Missed psychometric data may have led to OMs being wrongly excluded from the strategic list during psychometric evaluation.

Furthermore, the strategic list selection focused only on test-retest reliability as the basis for reliability evaluation. Selected OMs were those with ICC>0.9, or those that had the highest test-retest reliability within OMs measuring a construct. These were deemed the most appropriate for tracking individual change. If other reliability factors were prioritized such as internal consistency or inter-rater reliability, the OMs selected for the strategic list may have been different.

Additionally, the primary population at API drove strategic-list selection. Further evaluation of OMs appropriate for alternate populations (UE, Paediatric) should be completed as development of a comprehensive prosthetic OM app continues.

Future Research Considerations

Further psychometric evaluation into the OMs selected for the strategic list in part 2 would provide increased support for this selection. Specifically, support for inter-rater reliability is required for transferability of this list to other facilities in which more than one practitioner is measuring OMs for one patient.

The overarching goal of this project is to develop a prosthetic OM app suitable for use in all prosthetic facilities. This goal requires further evaluation of all OMs on the primary list, including OMs recommended for upper-extremity amputation and paediatric populations.

Benefits for Clinical Practice

The purpose of this research is to inform the development of a prosthetic OM application (app) for smart-devices. The goal of a prosthetic OM app is to reduce the barriers to outcome measurement currently reported in order to facilitate the routine use of OMs in prosthetic clinical practice. The hypothesized benefits of a well-developed app include:

1) The app will reduce the barrier of finding and interpreting research to select appropriate OMs by providing the practitioner with a list and description of appropriate OM with strong psychometrics. These measures will be categorized in the app by patient population, construct (function, mobility, QoL, satisfaction), and method of administration.

2) Lack of time is the most commonly reported barrier for using OMs. Even for a practitioner who is experienced at locating and analyzing OMs, selecting the appropriate one for a given clinical scenario is a time consuming process. The app will reduce the time barrier by providing the OM administration guidelines, supplies list, and scoring criteria.

3) The app will further reduce this time barrier by providing easy 1-step export to the patient's electronic health record (EHR) for enhanced efficiency of tracking and monitoring patients scores.

Future Steps

Development of the smart-device application software is underway concurrently with this research. Several practitioner created surveys have been added to the app for initial software testing. So far, surveys have been successfully completed within the app by a practitioner on several different smart-devices (apple iPAD, Android tablet, and Nexus 5 smart-phone). Survey results have been smoothly exported to P&O Expert (EHR software).

The next steps in app development include adding the OMs from the strategic selection of this review. Their creators must first approve these OMs for use in the app. Once the strategic OMs are added to the app, initial testing with patients can begin. An initial trial with three patient completing one performance and one self-report OM each, will gather patient feedback, assess initial ease of use, and identify problem areas. Improvements will be made to the app as needed.

Conclusion

This review outlines a primary list of 28 OMs that are suitable for use in prosthetic clinical practice based on current literature evidence [8,15,16,18,19,20]. This primary list is a starting point, and includes measures with varying levels of reliability. Further psychometric review is recommended to determine the strongest OMs for specific prosthetic populations and clinical situations.

Part 2 of this review summarizes the reported test-retest reliability, construct validity, and minimal detectable change for 8 OMs strategically selected for inclusion in a prosthetic OM smart-device application to be piloted at Atlantic Prosthetics Inc. From the primary list of 28, 8 were selected for the "strategic list". These 8 OMs were found to be the most valid and appropriate for evaluating function, mobility, quality of life, or satisfaction in persons with lower limb amputation. Six of these OMs (PEQ-MS, 6MWT, AMPPRO, PCI, PLUS-M™, ABC Scale) have excellent test-retest reliability (ICC>0.9), suggesting they are reliable enough to evaluate change in specific individuals over time. The OPUS-HRQOL© and TAPES-R have the highest test-retest reliability (ICC> 0.85) among OMs for QoL and PS respectively. Additionally, minimal detectable change values are reported for these 8 OMs; these are included in Table 3b of this review. Further review of inter-rater reliability would support these OMs in clinical settings where more then one rater will be utilized.

The development of this strategic list will contribute to the development of a prosthetic OM app for smart-device applications, to reduce the barriers to outcome measurement and facilitate more routine use of OMs in prosthetic clinical practice. Psychometric review of all OMs on the primary list of 28, would reveal the OMs most suitable for individuals with upper-extremity amputation, and the paediatric amputee populations. As development continues, OMs most suitable for other amputee populations will be added to the app.

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Comments of Personal Learning and Insights:

This research project was a good experience for me. I had minimal research experience previously and built greatly upon this knowledge. I learned a lot about the research process itself including: developing a search strategy and search terms, completing a literature review efficiently in several databases, and compiling and sorting data in excel. I also deepened my knowledge of outcome measures (OMs) and psychometric properties. I was exposed to all the OMs suitable to prosthetic practice, and investigated these for appropriateness, reliability, validity, and responsiveness. This will contribute to my continued work on an OM app. Beyond the direct development of the app, this new knowledge will enhance my ability to easily select OMs appropriate for my clinical practice.

The greatest challenge was finding time to complete all the goals I set out to do. I found myself narrowing the scope of the project as I realized how large it was. I think isolating a small area of research to take on would have been better for my first full research project, but I am glad I undertook this challenge and gained a lot of wisdom from it!