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Clinical Outcome Measures for Rehabilitation of Amputees – A Review

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Abstract

Prosthetic outcomes are determined by the prosthesis as well as by amputee specific factors - such as functional level and confidence - which affect performance with the device. The need to measure rehabilitation outcomes has become critical in the current healthcare environment. However, application of outcome measures by clinicians is limited due to their unfamiliarity with reliable and valid measures. This article provides a review of clinical outcome measures for assessing quality of life and functional ability during amputee rehabilitation and highlights the importance of incorporating outcome measurements in daily clinical practice. By utilizing outcome measures clinicians can not only determine the effectiveness of their intervention, but alsodemonstrate the value of the intervention to the patients and to third-party payers.

Keywords: Prosthetics; Outcome measures; Rehabilitation; Amputees

Background

Healthcare outcomes – by definition – are the changes in patients' health status, behavior and satisfaction which can be attributed to the treatment they received. Prosthetic outcomes can be defined as changes in the functional level, health and quality of life of amputees attributable to the prosthetic device [1]. As a result, outcomes with prosthesis are not only determined by the prosthesis itself, but also by patient specific factors such as their functional level. A well-fitting socket along with technologically advanced components does not guarantee optimal performance because – contrary to popular belief – a prosthes is not a device that is simply replacing a missing body part. It is a medical appliance that can significantly impact the users' health and quality of life. While a good fitting prosthesis is essential for optimal performance, factors related to function and confidence also alter an amputee's performance with prosthesis and can therefore influence outcomes.

The need to measure and evaluate rehabilitation outcomes has become critical in the current healthcare environment and would be required for reimbursement by third party payers in the near future. Despite the emergent need and the importance of outcomes measures for assessing rehabilitation performance, their applications by clinicians have been limited. The minimal use of outcome measures in prosthetic clinics can be attributed to (i) limited knowledge on the availability of reliable and valid outcome measures and (ii) unfamiliarity with the appropriate measures and (iii) lack of confidence in administering the measures. Clinicians are more familiar and comfortable using "clinical measures" and have a tendency to confuse clinical measures for "standardized outcome measures". Clinical measures require professional knowledge for interpretation, and may not always predict the outcomes that are important to the patient or may correlate poorly with standardized measures. Therefore, the purpose of this article is to review common clinical outcome measures that can be used to enhance amputee rehabilitation in a clinic.

Methods

A comprehensive search on outcome measures for amputee rehabilitation was performed on Medline and Google Scholar databases. The focus of the search was to identify outcome measures that assess function and quality of life in amputees. The articles returned through the search results were then thoroughly reviewed to select outcome measures that were developed specifically for amputees or were widely utilized for the amputee population. Following identification of the outcome measures, expert opinion was sought to select measures that were easy to administer and required limited resources, such that they could be easily implemented in a clinical setting. The outcome measures thus identified were then divided into the three principal categories of measurement instruments i.e. (A) self-report measures or patient-reported outcomes, (B) performance-based measures and (C) biomechanical measures.

Results

The commonly used outcome measures for assessing quality of life and functional abilities of amputees, which can be easily implemented in a clinical setting are listed below.

(A) Self-report measures or patient-reported outcomes

These are reports directly from the patients, which reflect their preferences and perceptions. They assess constructs such as symptoms, satisfaction, function, health perceptions and quality of life.

A1) Amputee activity survey [2]**:** This survey consists of questions which assess use of prosthesis, employment details, use of assistive devices, walking habits and social activity. The answers can have a positive or negative score and sum of the total score is calculated to obtain the overall "activity score". The activity score can range from a -70 to +50, with a score greater than 30 indicating very high activity and a score less than -40 indicating no activity. The administration time for this survey is approximately 15 minutes.

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A2) Prosthesis evaluation questionnaire (PEQ) [3]**:** It consists of 82 questions which describe the function of lower prosthesis and assess prosthesis related quality of life. The questionnaire is divided into 10 functional scales addressing four major domains, i.e. prosthetic function, mobility, psychosocial experience and well-being. There are seven groups of questions, which can be used and scored independent of the others. A subset of the PEQ, called to PEQ – Mobility Scale (PEQ_MS) consists of 12 questions and was designed to assess the locomotor ability while using prosthesis.

A3) Prosthetic profile of the Amputee [4]**:** The purpose of this questionnaire is to evaluate two constructs – (1) prosthetic use in terms of frequency of prosthetic wear and (2) the level of ambulatory function with the prosthesis. The 44 questions are grouped into six basic sections i.e.: the physical condition, the prosthesis, the prosthetic capabilities, the environment, the leisure activities and demographic characteristics. It should be noted that a composite score cannot be calculated for the six sections. This questionnaire is available in six different languages and takes about 25 minutes to administer.

A4) Locomotor capabilities index [5]**:** This questionnaire evaluates the level of independence when performing ambulatory activities and provides a composite score for basic and advanced activities. It consists of 14 questions which measure the patients perception on performing various activities, either independently or through assistance from a caregiver or ambulation aids. The questionnaire is available in seven different languages and can be administered in 5 minutes either over the telephone or in person.

A5) Orthotic prosthetic users' survey [6]**:** There are 4 components of OPUS (i) Lower limb functional status component: It consists of 20 questions which assess activities of low, moderate and high difficulty. The activities are rated on a 5 point scale ranging from "very easy" to "can't perform activity". (ii) Quality of life component: It consists of 23 questions, which relay higher average and low quality of life aspects. The questions are rated on a 5 point scale ranging from "not at all" to "extremely". (iii) Satisfaction with device component and (iv) Satisfaction with service component consists of 11 questions and 10 questions respectively. Questions for both of these components are rated on a 4 point scale ranging from "strongly agree" to "strongly disagree".

The OPUS questionnaire also has a module for evaluating the functional status of the upper extremity while performing various activities. The upper extremity functional status (UEFS) scale is a self-report measure for assessing the ease of performing 23 self-care and instrumental activities of daily living [7]. The patients respond by using a five-point rating scale which ranges from 0 (cannot perform activity) to 4 (very easy to perform the activity).

A6) Trinity amputation and prosthesis experience scales (TAPES) [8]**:** This questionnaire has been designed to assess adjustment to a prosthetic limb, by incorporating the physical and psychosocial aspects of adjustment. It consists of 40 to 60 questions related to psychosocial adjustment, activity restriction and prosthetic satisfaction domains. The total number of questionsvary depending on the choices made by the patient. The questionnaire is divided into two parts, which use a combination of a 5 point rating scale (strongly agree-strongly disagree), a 3 point rating scale (not at all limited to limited a lot) and "yes/no" responses. It can be used to evaluate changes in quality of life during the rehabilitation process.

A7) Prosthetic limb users survey (PLUS) [9]**:** It is a collection of outcome measurement instruments that are currently being developed with the intention of measuring attributes of mobility balance and dexterity. The first subset called the PLUS-M was developed in 2012 and is currently undergoing longitudinal testing. The current version of PLUS-M includes 12 questions which assess mobility with a prosthetic leg and are answered on a 5 point scale ranging from "unable to do" the activity to "without any difficulty".

A8) Disabilities of the arm, shoulder and hand (DASH) [10]**:** This measure is used to assess the impact of upper extremity amputation on physical function and can also be used to observe changes in function and symptoms over time. It consists of 30 questions, which are scored using a five-point scale from 1-5, where a score of 1 represents "no difficulty" in performing the activity and 5 represents inability to perform the activity. A composite score for all 30 items is calculated, with a higher score indicating greater disability or greater functional limitation.

(B) Performance-based measures

These measures evaluate the performance of patients during a task or a group of tasks. Performance is scored in terms of either the time needed to complete the task, the distance covered, or their ability (inability) to do the task. The result of these measures is typically a number which can be compared across different patients or for the same patient at different time intervals during the rehabilitation process.

B1) Amputee mobility predictor (AMP) [11]**:** The AMP is a measure of the functional ambulation capabilities of people with a lower limb loss. It can be performed by patients with or without using prosthesis (AMPPRO and AMPnoPRO respectively). It consists of 21 tasks, classified into four categories i.e., sitting balance, simple mobility, standing balance and gait and functional activities. This questionnaire can be administered in 10 to 15 minutes.

B2) Comprehensive high-activity mobility predictor (CHAMP) [12]**:** It is a measure of agility typically used to test and high level performers who tend to max-out their ratings on other performance-based measures. This measure includes activities like turning, cutting, side to side movement, and backward running which are designed to test motion in all three planes. It consists of five tasks and can be administered in 10 to 15 minutes.

B3) Timed up and go test (TUG) [13]**:** Originally the TUG was designed to test basic mobility skills of frail elderly persons. It is now being increasingly utilized to test functional mobility in a wide variety of patients, such as people with a lower limb loss and stroke. While performing the test the patient is asked to stand up from a chair, walk 10 feet turn and return to the chair and sit on the chair. This measure this tests a number of tasks which are essential for mobility, such as standing from a seated position walking turning and sitting down on the chair.

B4) Six minute walk test (6MWT) [14]**:** The purpose of this test is to evaluate functional capacity as the individual walks for 6 minutes on a hard, flat surface. The goal for patients is to cover as much

distance as possible in 6 minutes, by pacing themselves and resting as needed. A variation of this test is the 2 minute walk test, during which the patient is asked to walk for 2 minutes. The 6 minute walk test can also be used to detect changes in physical activity following an intervention [15].

B5) Southampton hand assessment procedure (SHAP) [16]**:** The SHAP is a hand function test which was originally developed to assess the effectiveness of upper limb prosthesis. The individual is asked to perform 26 tasks – 14 activities of daily living and 8 tasks with abstract objects – which are classified into six prehensile patterns. The time needed to complete each task is recorded and a composite score is generated. Scores less than 100 indicate impairment in hand function.

(C) Biomechanical measures

The biomechanical outcome measures can be classified as kinematic, kinetic and temporal-spatial parameters. While it may not be possible to measure all outcomes in a clinical setting, recent advancements in wireless technology and mobile computing has led to the development of clinically friendly equipment that can measure selected biomechanical parameters.

C1) Symmetry in external work (SEW) measure [17]**:** It is a measure of the gait dynamics which assesses the symmetry of work between lower limbs i.e. the effort provided by each limb in moving the body during ambulation. It can be calculated easily using in-sole sensors and with minimal attachments on the patient. This is a reliable and valid measure that can assess the biomechanics of activities such as level ground walking and ramp and stair ambulation. The SEW measure has been used to detect functional differences between different prosthetic feet [18-20], and could easily be employed in a clinical setting.

Discussion

The outcome measures reviewed above represent the most common clinical measures that can be used for assessing the quality of life and functional abilities of amputees during the rehabilitation process. While a number of outcome measures are available for clinical use, a vast majority of instruments have not been developed specifically for the amputee population. Functioning with a prosthesis involves complex interactions between the human and machine (i.e. the prosthetic arm or leg), and introduces unique challenges for the rehabilitation clinician. Although outcome instruments that have been developed for a different population have been utilized in amputees, these measures may be of limited clinical use, as they are not able to assess issues of importance that are explicit for amputees. This review therefore focuses on those outcome measures that have been developed exclusively for the amputee population, or have been used extensively in this population.

This review also identifies outcome measures that aresimple to administer and require limited resources, and could therefore be easily implemented in a clinical setting. Prosthetic outcomes related to functional mobilityand quality of life issues that are most relevant for amputee patients can thus be assessed by the rehabilitation clinician by using one or more of these measures. Some of the validated measures may be limited in their ability to effectively assess the attributes of interest and may not have significant value for a particular patient. In such cases, it is usually beneficial to use the most appropriate validated outcome measure and supplement it with an additional outcome instrument. By incorporating outcome measures in daily practice clinicians can have the ability to evaluate the various aspects of clinical care such as level of confidence with the prosthesis, socket comfort, functional level and quality of life with the prosthesis. Outcome measures not only help clinicians to determine the effectiveness of an intervention but they can also detect the cause of the problem and in some cases provide directions on potential solutions and therapeutic interventions. Through outcomes measurement, clinicians can assess the value of the treatment for patients and demonstrate to the caregivers and insurers the extent to which the treatment brings about improvement in health.

Conclusion

Measurement of outcomes is a systematic approach for evaluating the quality of care, and effectiveness of treatment that clinicians provide to patients with amputations. Reliable and valid outcomemeasures can act as powerful tools not only for improving clinical care but also for justifying the plan of treatment to third party payers. By utilizing the appropriate outcome measures, clinicians will be able to get an overall idea of the health outcomes in amputee patients, improve prosthetic performance and satisfaction and reduce the per capita cost of treatment.

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