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Clinically Relevant Outcome Measures in Orthotics and Prosthetics

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Introduction

The culture of third-party reimbursement for medical services is changing. Increasingly, providers throughout the healthcare industry are called upon to validate the benefit and efficacy of the services they provide. As prosthetists and orthotists, we have historically been less scrutinized in this regard, as the tangible devices we supply have often been looked upon as an "outcome" in and of themselves. However, with the growing emphasis on the importance of outcomes assessment, it will become increasingly necessary for clinicians in O&P to be able to select and administer those accepted outcome measures that will best justify our interventions.

This article outlines a selection of outcome measures that have been found to be both valid and reliable for many of the patient populations encountered within our practices. These include fairly simple performance measures, including the ten-meter walk test (10mWT) and six-minute walk test (6MWT); slightly more involved performance measures, including the timed up-and-go (TUG) and the L-Test of functional mobility; and comparatively elaborate performance measures including the modified-Emory Functional Ambulation Profile (mEFAP) and the Amputee Mobility Predictor (AMP). In addition to these performance-based instruments, self-report measures will also be introduced, including the Activities-specific Balance Confidence scale (ABC), the Locomotor Capabilities Index (LCI), the Socket Comfort Score (SCS), and the Ankle Osteoarthritis Scale (AOS).

The strengths and weaknesses of these measures will be presented to enable the busy practitioner to better select the measures that will best validate the intervention in question. In addition to their validity and reliability, the measures presented were chosen for their clinical applicability. They are comparatively quick and simple to administer, requiring little more than a chair and a stop watch or access to a copy machine. As

such, this article is intended as a primer in the incorporation of standardized outcome measures into a busy O&P clinical practice.

Performance Measures: Timed Walking Tests

10mWT

Among the timed walking tests, perhaps the simplest to administer is the ten-meter walk test (10mWT). As the name implies, it is simply a documented measure of the time required for the patient to traverse ten meters at his self-selected walking speed. Properly administered, the test is performed with a flying start and finish. Specifically, the patient should be allowed several meters of ambulation immediately before and after the ten-meter walkway to ensure that there are no periods of acceleration or deceleration within the timed event itself. Additionally, clinicians should walk behind the patient rather than at his or her side or in front of him or her to ensure that they are not pacing the patient at a speed other than the patient's true, self-selected walking speed.

Relative to our profession, the 10mWT was first reported among a cohort of chronic stroke patients,[1] where it was concurrently validated and found to have good interrater reliability (administered by two separate clinicians) and intrarater reliability (administered on two separate occasions). It has since been reported among populations with both chronic and acute stroke[2] and the rather heterogeneous populations of patients with spinal cord injury (SCI)3 and "neurological impairment."[4] Given the tremendous variability in the levels of disability encountered in these latter patient groups, it is not surprising to observe equivalent variability in their times for the 10mWT. As an example, time values for patients with SCI ranged from six seconds to 190 seconds.[3] However, good individual interrater and intrarater reliability was demonstrated for the measure.[3] Given the comparative homogeneity observed within the stroke population, an awareness of the mean times of the acute and chronic subpopulations within this broad patient group may be of some clinical value and are shown in Table 1. This paper is of particular interest, as the two cohorts performed the 10mWT both with and without an off-the-shelf ankle-foot orthosis (AFO).[2]

Table 1: 10mWT for Patients with CVA

Population	Mean 10mWT
Chronic Stroke	16.4 s
Chronic Stroke with AFO	14.1 s
Acute Stroke	17.2 s
Acute Stroke with AFO	14.5 s

Derived from Wang et al., 05.

6MWT

An understanding of the value of the six-minute walk test (6MWT) with respect to outcomes assessment is perhaps best gained through an appreciation of its history. It was originally designed as a "useful measure of exercise capacity" by researchers working with patients demonstrating chronic heart failure.[5] Accordingly, while the 10mWT test provides useful information regarding self-selected walking speeds over short

distances, the 6MWT begins to address questions of endurance during ambulation. As a relevant example, Geboers et al. evaluated a cohort of patients with foot drop, walking with and without their AFOs.[6] When they were assessed using the 10mWT, no significant improvements were observed with the addition of the orthosis. However, when the researchers evaluated the same group of patients using the 6MWT, the addition of the orthoses resulted in significant improvements. The most plausible explanation for these results lies in the ability of many patients with foot drop to compensate for their gait deficits over short distances but not over extended periods of activity.

As the names implies, the 6MWT is simply a record of the distance traveled by a given patient at his or her self-selected walking speed over a period of six minutes. All that is required is a stopwatch and a walking corridor or track of known distance. As with the 10mWT, those administering the test should avoid walking with or in front of test subjects to avoid pacing individuals outside of their self-selected walking speed.

The reliability and/or concurrent validity of this assessment have been verified and reported in populations with SCI,[3] chronic cerebral vascular accident (CVA),[7] traumatic brain injury (TBI),[8] and lower-limb amputation.[9] While some of these patient groups are quite heterogeneous, there is still clinical value in examining the reported means, standard deviations, and ranges that have been reported with this measure (see Table 2).

Table 2: 6MWT Among Various Patient Populations

Population	Mean ± SD (m)	Range (m)
Spinal Cord Injury*	205 ± 120	23-475
Chronic CVA**	202 ± 88	N/A
Traumatic Brain Injury+	403 ± 105	155-660
Lower-Limb Amputee (K0-K1)^	50 ± 30	4-96
Lower-Limb Amputee (K2)^	190 ± 111	16-480
Lower-Limb Amputee (K3)^	299 ± 102	48-475
Lower-Limb Amputee (K4)^	419 ± 86	264-624
Healthy Elderly Adults**	417 ± 95	N/A

Taken from: *van Hedel et al., 05; **Ng et al., 05; + Mossberg et al., 03; ^ Gailey et al., 02.

2MWT

While the 6MWT is more commonly found in peer-reviewed investigations, some work has been done to investigate the value of the two-minute walk test (2MWT) among lower-limb amputees. Citing its value as "the fastest and most efficient measure among the timed walk tests," Brooks et al. published two papers reporting on the utility of the 2MWT.[10-11] In the first, the authors demonstrated the measure's responsiveness to rehabilitation by reporting the mean values collected from a cohort of 290 lowerlimb amputees: (a) following the initial fitting of the prosthesis; (b) within 48 hours of the patient's discharge from an inpatient rehabilitation admission; and (c) at the patient's three-month outpatient follow-up (Table 3).[10] In their second paper, the authors investigated the interrater and intrarater reliability of the 2MWT, reporting high intraclass correlation coefficient (ICC) values for both.[11] Finally, in a separate investigation, Miller et al. reported on

mean 2MWT values for a cohort of "prosthetically and medically stable" patients (Table 3).[12]

Table 3: 2MWT for Lower-Limb Amputees Undergoing Inpatient Rehabilitation

Assessment	Mean ± SD m
Baseline*	27.9 ± 18.1
Discharge*	41.1 ± 28.5
3 Month f/u*	69.6 ± 40.9
Legacy Outpatient+	99.2 ± 15.1

Taken from * Brooks et al., 01; + Miller et al., 01.

Additional Considerations

The usefulness of these simple, timed walking tests should not be underestimated. One of the objectives of outcomes assessment is quantifying changes in patient ability and performance. Doing so requires an instrument that is sensitive enough to register even small improvements and that will continue to recognize improvements throughout a patient's rehabilitation without encountering a ceiling effect.

The ability of simple, timed walking tests to address these criteria is well illustrated in a recent study by van Hedel et al.[13] The authors examined a cohort of patients with incomplete SCIs as they regained their walking capacity. In doing so, the authors monitored improvements in function using the Walking Index for Spinal Cord Injury II (WISCI II). This outcome measure was selected because it had been shown to be more responsive than similar measures including the Barthel Index, the Rivermead Mobility Index, and the Functional Independence Measure. In addition, the authors took repeated measures of both the 10mWT and the 6MWT. While the WISCI II was able to measure improvements between the first assessment taken within one month of the original injury and a follow-up assessment three months later, the WISCI II values obtained at the six- and 12-month follow-ups failed to demonstrate significant improvements. This was due to a ceiling effect as patients reached the maximum performance values of the WISCI II within the initial few months of their rehabilitation. In contrast, the timed walking tests continued to demonstrate improvements in patient walking capacity at the three-, six-, and 12-month follow-up assessments. Put more succinctly, these simple, timed walking tests appeared to be more responsive to patient changes across a broader range of functional ability than several of the more complex and time-consuming outcome indices.

Timed Walking/Transfer Tests

TUG

Timed walking tests measure one of the most basic functions of day-to-day life. However, they fail to address the fundamental notion of position transfers, such as turning, rising from sit to stand, or returning to a seated position. Measures of similar simplicity have been developed to examine these activities as well.

The most frequently used is the timed up-and-go (TUG). In this outcome measure, the patient rises from a seated position, walks three meters at a self-selected speed, turns around, and returns to the chair where he

reseats himself. As with the earlier measures, it is simply a timed event with the clinician timing from the moment the patient leaves the chair until he is reseated.

The reliability and concurrent validity of this assessment measure have been verified and reported in populations with lower-limb amputation,[14] chronic CVA,[7] and SCI.[3] It has been used to determine the treatment effect of AFOs on patients with chronic CVA[15] and to validate other outcome measures among lower-limb amputees.[12] A summary of reported means and standard deviations is shown in Table 4. In observing the disparity between the two amputee cohorts, it should be noted that the cohort reported upon by Schoppen et al. were on average 15 years older than those reported upon by Miller et al. (73.3 and 58.4 years old, respectively).[12-13] Additionally, the amputations within Schoppen's cohort were exclusively due to peripheral vascular disease, while Miller's cohort was made up of both vascular and non-vascular amputees.[12-13] The disparity between the two CVA cohorts may be partially explained in that the cohort of de Wit et al. was composed exclusively of patients who regularly used AFOs for ambulation, while the majority of those in the cohort of Ng et al. did not require lower-limb bracing.[7,14]

Table 4: TUG Values Among Various Patient Populations

Population	Mean ± SD (s)
Chronic CVA (Ng et al)*	22.6 ± 8.6
Chronic CVA (de Wit et al)**	29.2 ± 12.9
Chronic CVA w/ AFO**	25.6 ± 11.7
Spinal Cord Injury+	36.0 ± 27.0
Transtibial Amputation (Shoppen et al)^	23.1 ± 23.0
Transfemoral Amputation(Shoppen et al)^	28.3 ± 12.2
Lower-Limb Amputee (Miller et al)#	19.3 ± 15.1
Healthy Elderly Adults*	9.1 ± 1.6

Taken from * Ng et al., 05; ** de Wit et al., 04; + van Hedel et al., 05; ^ Shoppen et al., 99; # Miller et al., 01.

L-Test of Functional Mobility

Citing the existence of a ceiling effect when using the TUG to assess function in younger, more physically fit lower-limb amputees, Deathe et al. reported on a modified version of the TUG, which they called the L-Test of Functional Mobility.[16] The revised measure is practical in design and intended to be used in a standard clinical hallway. The patient begins the test seated in a chair, ideally positioned in an exam room and facing the entrance to the hallway. The patient rises from the chair, walks three meters into the hallway, turns 90 degrees and then walks an additional seven meters down the hallway. Upon completing seven meters, he turns 180 degrees, returns down the hallway, turns 90 degrees to face the exam room, and returns the three meters to his chair, where he retakes his seat. With these modifications, the new outcome measure requires ambulation over 20 meters, two transfers, and three turns. As with the TUG, it is a timed event from the moment the patient rises from his chair until he returns to a seated position, all the while walking at a self-selected speed.

The authors found this new instrument to demonstrate concurrent validity when compared with other

outcome measures, as well as good interrater and intrarater reliability.[16] The authors also reported the measure's standard error of measurement at three seconds. Thus, if a patient's time to complete the L-Test changes by more than three seconds, clinicians can be confident that a real change in function has occurred. Additionally, the authors found less of a ceiling effect with this measure than that observed with the TUG. The authors reported mean and standard deviation values for the L-Test within several subgroups of the amputee population (Table 5).

Table 5: L-Test Values for Lower-Limb Amputees

Cohort	Mean ± SD (s)
Transtibial	29.5 ± 12.8
Transfemoral	41.7 ± 16.8
Traumatic	26.4 ± 7.8
Vascular	42.0 ± 17.8
Walking Aid Used	25.5 ± 6.4
No Use of Walking Aid	43.3 ± 17.5
<55 Years Old	25.4 ± 6.8
>55 Years Old	39.7 ± 17.1

Taken from Deathe et al., 05.

Aggregate Tests

mEFAP

The next logical step is to evaluate a few outcome measures that assess functional abilities in a broader context than those presented so far. The modified Emory Functional Ambulation Profile (mEFAP) is one such measure, evaluating ambulatory function across a range of simple tasks.[17]

The measure is an aggregate of five timed walking activities: (1 and 2) Five-meter walks across a "hard-surfaced floor" and "pile carpet" respectively. Timing begins when the patient begins to walk the prescribed distance. However, deceleration is eliminated from these measures as patients "walk through" the finish line. (3) TUG as defined earlier. (4) "Obstacles," administered as follows: A one-meter piece of tape on hard-surfaced floor marks starting/finishing point. A brick is placed on the floor at the 1[illegible] meter mark and three-meter mark. A 40-gallon trash can is placed at the five-meter mark. The following instructions are given: "When I say 'go,' walk forward at your normal, comfortable pace and step over each brick. Then, walk around the trash can from either the left or right. Then walk back, stepping over the bricks again. Continue walking until I say 'stop.'"[17] (5) "Stairs," using four steps with hand railings and a start line indicated 25 centimeters from the base of the first stair. The following instructions are given: "When I say 'go,' walk up the stairs at your normal comfortable pace to the top of the stairs, turn around, and come back down. You may use the handrails if needed. I will follow behind you for safety."[17] Timing ends when the trailing limb establishes firm contact with the floor after descending the final step. The final mEFAP score is the sum of the times required to complete the five tasks.

The mEFAP was originally developed within the stroke population, where it was found to demonstrate good interrater and intrarater reliability and concurrent validity.[17] A later study confirmed these findings, while also reporting good responsiveness to change for the instrument.[18] It has been used to quantify improvements gained during inpatient rehabilitation,[17] to quantify the positive impact of AFOs among chronic CVA patients,[19] (Table 6) and to suggest functional therapeutic improvements associated with sustained daily use of a surface peroneal nerve functional electrical stimulation unit in patients with chronic CVA.[20]

Table 6: mEFAP Values for Patients with Chronic CVA, with and without AFOs

Event	No device (s)	With AFO (s)
5 m Floor	15.1	12.2
5 m Carpet	14.2	11.6
TUG	31.3	28.3
Obstacles	44.4	38.7
Stairs	24.0	21.6
Total	129.0	112.4

Taken from Sheffler et al., 06.

AMP

The Amputee Mobility Predictor (AMP) is a 20-item scale that was originally developed to provide a more objective approach to the assignment of Medicare K-levels.[9] In doing so, it was designed to measure patient capabilities both with (AMPPRO) and without (AMPnoPRO) a prosthesis. The resulting instrument requires ten to 15 minutes to administer and is intended for use by physicians, prosthetists, and physical therapists. The items within the instrument are organized with increasing levels of difficulty, including tasks intended to assess sitting balance, transfers, standing balance, gait, and obstacle negotiation. Each task is graded in a defined but simple way with 0 indicating inability, 1 suggesting that some assistance was required or the task was minimally performed, and 2 implying independence or mastery of the task. A full description of the individual tasks along with the scoring matrix is available in the original article[9] or in the third edition of the *Atlas of Prosthetics*.[21]

The instrument was found to have good interrater and intrarater reliability as well as concurrent validity.[9] A list of mean AMP values for cohorts of the various Medicare K-levels is shown in Table 7. Importantly, while the mean AMP values between K-levels differed, the authors were clear in reporting that considerable overlap existed between the cohorts and that they were unable to establish clear cut-off values for the assignment of K-levels. However, in the current healthcare system, with its growing interest in objective assessments and measures, it seems likely that the objectivity of the AMP or similar tools may ultimately be called upon to support the rather subjective assignment of K-levels.

Table 7: AMPPRO and AMPnoPRO Values for Lower-Limb Amputees According to Medicare K-levels

K level	AMPnoPRO: Mean + SD	AMPPRO Mean + (SD)
K0-K1	9.7 ± 9.5	25.0 ± 7.4
K2	25.3 ± 7.3	34.7 ± 6.5
K3	31.4 ± 7.4	40.5 ± 3.9
K4	38.5 ± 3.0	44.7 ± 1.8

Taken from Gailey et al., 02.

Additional Considerations

While the tests described in this section evaluate a broader spectrum of functional abilities than those presented earlier, it should not be assumed that they will capture every benefit that a patient might experience from a given intervention. This principle is demonstrated well in a recent study by Sheffler et al., in which the mEFAP was administered to a cohort of patients with multiple sclerosis, both with and without their existing AFOs.[22] The authors found no significant differences in mEFAP scores between either individual task or aggregate performance times in the two conditions.

However, the shortcomings may have lain more with the selected outcome measure than with the orthotic interventions. In defining their inclusion criteria for the study cohort, the authors stated that "each subject had sufficient endurance and motor ability to ambulate a minimum of 30 feet continuously with minimal assistance or less without the use of an AFO."[22] Given that the study participants had all demonstrated the ability to compensate their walking mechanics without an AFO for a minimum of ten meters, it can hardly be surprising when an aggregation of timed five-to-six-meter events failed to demonstrate significant differences.

This example highlights the importance of selecting those outcome measures that are most likely to capture the anticipated changes in function. For the patient population considered above, each of whom had demonstrated an ability to accommodate walking over short distances without lower-limb bracing, outcome measures designed to assess walking endurance or balance may have better demonstrated the potential benefits of the orthotic intervention. Hence, an awareness of multiple outcome measures and what they are designed to assess can empower the clinician to appropriately quantify the changes in function associated with a given intervention.

Self-Report Instruments Ability

LCI and LCI-5

In contrast to the AMP, in which the patient is required to physically demonstrate a set of defined tasks, the Locomotor Capabilities Index (LCI) is a means of documenting an amputee subject's perception of his own capabilities. The LCI began as a subset of the more exhaustive Prosthetic Profile of the Amputee.[23] As with the AMP, the LCI reports across a range of tasks including both transfer and ambulation activities. In its original form, the subject rates his ability to perform 14 tasks. The first seven tasks are considered basic, such as "get up from a chair," and "step down a sidewalk curb." The subsequent seven tasks are considered more advanced, such as "walk while carrying an object" and "walk outside on uneven ground." Each item is scored on a four-point ordinal scale according to the level of independence the subject reports for the performance of each task.

In response to the original instrument's strong ceiling effect, reported by one author as 40 percent,[12] Franchignoni et al. developed a modified version of the LCI in which another level of performance is established.[24] The resulting instrument, referred to as the LCI-5, allows the patient to select one of five levels of performance in addressing his ability to accomplish the various items: No (0); Yes, if someone helps me (1); Yes, if someone is near me (2); Yes, alone, with ambulation aids (3); and yes, alone, without ambulation aids (4). The original LCI can be found on page 63 of the proceedings of the American Academy of Orthotists and Prosthetists State of the Science Conference on "Outcome Measures in Lower-Limb Prosthetics." This document is available online at www.oandp.org/jpo/library/2006_01s_061. The LCI-5 is easily constructed by modifying this resource to allow the five different responses as indicated above. It is also indexed in the original article by Franchignoni et al. and can be openly accessed at www.inail.it/repository/contentmanagement/information/n1609925963/lcI6.pdf. Both items have demonstrated good interrater and intrarater reliability.[12, 23–24]

Balance

ABC

The Activity-specific Balance Confidence Scale (ABC) was originally developed for use in the geriatric population to quantify a patient's assessment of his or her own balance confidence. 25 The instrument is a 16-item questionnaire in which subjects rate their confidence in whether they will not lose their balance or become unsteady when performing a series of defined activities. These tasks range from very basic, such as "walk around the house" to more challenging, such as "walk outside on icy sidewalks." The reported confidence values are averaged for a total ABC score with a maximum possible value of 100 percent confidence.

Recognizing the inherent balance compromise associated with prosthetic ambulation, a team of researchers demonstrated the reliability and validity of the instrument within the lowerlimb amputee population.[26] Reported mean ABC values for various sub-cohorts within this population are shown in Table 8. Importantly, their research also identified a standard error for the ABC within the lower-limb amputee population of six points. This means that clinicians can feel confident that any change in a patient's reported ABC value of more than six points is beyond the range of measurement error and consistent with an actual change in balance confidence.

Table 8: ABC Values for Lower-Limb Amputees

Cohort	Mean ABC
Transtibial	64.9
Transfemoral	62.9
Vascular	50.6
Non-vascular	76.4
No Mobility Device	82.6
Mobility Device	47.6

Taken from Miller et al., 03.

In addition, the ABC has been studied within the chronic CVA population where it was found to be both valid and reliable with minimal floor or ceiling effects.[27] It received further evaluation within a cohort of patients who had all experienced their CVA within one year of the evaluation.[28] Mean ABC values from these studies are shown in Table 9. Its use has also been reported within the multiple sclerosis[29] and post-polio[30] populations. A copy of the ABC is available online at www.pacificbalancecenter.com/forms/abc_scale.pdf

Table 9: ABC Values for Cohort Populations of CVA Patients

CVA Cohort	Mean ± SD
< 1 Year Post CVA+	59 ± 21
No Walking Aid+	67 ± 21
Cane+	54 ± 18
Walker+	46 ± 21
> 1 Year Post CVA*	68 ± 18

Taken from + Salbach et al., 06 and * Botner et al., 05.

Pain/Disability

SCS

The Socket Comfort Score (SCS) was developed in an attempt to quantify the rather subjective experience of socket discomfort and pain.[31] It is based on the numerical rating scale (NRS) commonly used in pain clinics. However, because the scale assesses comfort rather than pain, the numerical values are reversed with higher SCS values assigned to a more comfortable socket fit.

The SCS is administered by asking the patient the following question: "If 0 represents the most uncomfortable socket fit you can imagine and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb at the moment?"[31] Despite its simplicity, the SCS has shown correlations between patient reports, clinical findings of the physician (redness, pressure marks, sores etc.), and the prosthetic fit as judged by the prosthetist.[31] The measure has also demonstrated sensitivity to change as socket adjustments and socket replacements aimed at improving comfort resulted in higher SCS values.[31] Ultimately, the SCS is intended to provide a level of standardization to a phenomenon that has historically been treated in purely descriptive forms.

AOS

The Ankle Osteoarthritis Scale (AOS) was developed by Domsic et al. to be a disease-specific, reliable, and valid instrument for measuring symptoms and disabilities related to ankle arthritis.[32] The resultant instrument consists of two portions assessing pain and disability, respectively. In the pain assessment, subjects rate the severity of their ankle pain from "no pain" to "worst pain imaginable" along a 100mm visual analog scale in each of nine situations such as "when you walked barefoot" and "at the end of the day. In the disability assessment, subjects rate the difficulty they experienced during nine defined activities along a 100mm visual

analog scale ranging from "no difficulty" to "so difficult, unable." The items include "walking around the house," "climbing stairs," and "walking fast or running."

The instrument was found to be both reliable and valid and has been used in a number of clinical trials to assess the efficacies of interventions, ranging from surgical techniques, injections, and joint distractions. Given its broad usage and acceptance, the AOS would be an ideal instrument to quantify the affect of foot and ankle orthoses within this patient population. The AOS can be found in the original article by Domsic et al.[32]

Concluding Thoughts

Given the current trends in healthcare, orthotists and prosthetists are under increasing pressure to more formally document the outcome of their interventions. Our situation is somewhat unique in healthcare in that we are currently unable to obtain reimbursement for the actual time spent interacting with patients. These realities make it increasingly important for practitioners to become familiar with accepted outcome measures, such as those presented above, which can be effectively administered in a low-cost, time-efficient manner.

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