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## Feature Clinically Relevant Outcome Measures in Orthotics and Prosthetics

A Case Study The Effect of an Ankle-Foot Orthosis MEDICAL CENTER ON Gait Parameters of Acute and Chronic Hemiplegic Subjects

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Contrange Measures

M.D

Two Continuing Education Opportunities in this Issue!

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# **Progress Abounds**

ne of the benefits of being president is watching the Board and dedicated members of the American Academy of Orthotists and Prosthetists (the Academy) make progress on Academy initiatives.

The growth of the Academy's societies has been impressive over the last three years. These seven specialty groups have increased their participation in the one-day seminars and have submitted additional *Journal of Prosthetics & Orthotics (JPO)* articles and additional presentations for the Annual Meeting and Scientific Symposium. Keith Smith, CO, LO, FAAOP, president-elect of the Academy, will complete his third year as society chair this June, and David Gerecke, CP, FAAOP, vice chair, is gearing up to take over the helm.

Last year, the societies elected new boards and new chairs for two-year tenures. Returning chairs include CAD/CAM Society Chair Randall Alley, BS, CP, CFT, FAAOP; and Upper-Limb Prosthetics Society Chair Chris Lake, CP, FAAOP. Catherine Voss, CO, moved from vice chair to chair of the Spinal Orthotics Society. The Lower-Limb Prosthetics Society is now chaired by Kevin Carroll, MS, CP, FAAOP. Barbara Ziegler, CPO, FAAOP, is chair of the Craniofacial Society; David C. Williams, CO, chairs the Lower-Limb Orthotics Society. The Gait Society chair is Susan Ewers, CPO.

This year, five societies submitted abstracts to be presented at the Academy's 35<sup>th</sup> Annual Meeting and Scientific Symposium, with the Gait and Upper-Limb Prosthetics Societies emerging successfully. The Lower-Limb Prosthetics Society recently helped with the Academy's one-day seminar in Chicago, Illinois, and the attendance was near capacity. All seven societies are working on submissions for future issues of *The Academy TODAY*.

Sam Phillips, PhD, CP, FAAOP, the Academy's Publications Committee chair, has worked closely with a couple of the societies to add to the recommended reading list available online at Amazon.com

The Paul E. Leimkuehler Online Learning Center (OLC) continues to establish itself as a premier spot for continuing education, and the societies are working to submit additional online content to the OLC. We hope every member will consider joining an Academy society.

The number of offerings on the Academy's OLC now total 92. If you want to learn new techniques or applications or simply want to increase your general knowledge but can't seem to find the time, the OLC is for you. Courses are available on your schedule. You decide when to view them, when to study, and when to take the proficiency exam. Not only is the timing yours, but so are the contents—in your own virtual library forever! The current "hot courses" are "Current Trends in Pediatric Practice"

and "Evidence-Based Practice." In addition, all eight State of the Science Conferences (SSCs) are on the OLC, along with

exams to test your knowledge of our profession's current body of knowledge.

If you are a business owner struggling with the costs of continuing education, consider the value offered by the OLC: no travel/hotel expenses, no time out of the office, and increased capability and knowledge for your clinical staff. The OLC



James P. Rogers, CPO, FAAOP 2008–09 President

is the economical way for forward-thinking business owners to leverage their continuing education dollars without letting travel to traditional meetings and symposia interrupt the revenue stream. Your employees can attend the Academy's Annual Meeting and Scientific Symposium each year and earn the rest of the credits they need online.

When I think of the positive energy flowing in and about the Academy today, I would be remiss if I failed to mention the Academy chapters. The chapters are the lifeblood of the Academy. More than 2,000 members attend chapter meetings each year. Nathan Seversky, CP, FAAOP, our newest board member and the new chapter chair, is looking forward to infusing his energy and creativity into the chapters. Nathan is working with Academy staff to explore creating a new page on the website dedicated to chapter affairs, which will allow chapter officers to communicate with each other on a more regular basis.

As we head toward an evidence-based model for clinical practice, we hope to work with our chapters to provide more educational content to help shape our paradigm. The Academy can assist in providing a format for journal clubs (a group of individuals who meet regularly to critically evaluate recent articles in scientific literature) and help connect chapters and individual practices with new graduate practitioners who are up-to-date with the literature and research-based clinical models. The Academy also looks to the chapters for emerging leaders and clinical and educational specialists to help further the education of the entire profession.

The national office staff and Clinical Content Committee have created the final program for the 35th Annual Meeting and Scientific Symposium in Atlanta, Georgia, March 4–7, 2009. I hope you plan to attend what has become the O&P profession's premier education conference. Atlanta is a great city and offers a wonderful variety of activities for you and your entire family.

## **Clinically Relevant Outcome Measures in Orthotics and Prosthetics**

 Phil Stevens, MEd, CPO, FAAOP Natalie Fross, Student Prosthetist Susan Kapp, MEd, CPO, LPO

#### 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 tenmeter 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 Activitiesspecific 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 tenmeter 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, selfselected walking speed.

Relative to our profession, the 10mWT was first reported among a cohort of chronic stroke patients,<sup>1</sup> 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<sup>2</sup> and the rather heterogeneous populations of patients with spinal cord injury (SCI)<sup>3</sup> and "neurological impairment."<sup>4</sup> 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.<sup>3</sup> However, good individual interrater and intrarater reliability was demonstrated for the measure.<sup>3</sup> 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 sixminute 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.<sup>5</sup> 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.<sup>6</sup> When they 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 (KO-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.

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,<sup>3</sup> chronic cerebral vascular accident (CVA),<sup>7</sup> traumatic brain injury (TBI),<sup>8</sup> and lower-limb amputation.<sup>9</sup> 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).

#### 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.<sup>10-11</sup> 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

#### 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.<sup>13</sup> 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

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*	<b>99.2</b> ± 15.1

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

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) $^{\wedge}$	28.3 ± 12.2
Lower-Limb Amputee (Miller et al) <sup>#</sup>	19.3 ± 15.1
Healthy Elderly Adults*	9.1 ± 1.6

Table 4: TUG Values Among Various Patient Populations

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

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,<sup>14</sup> chronic CVA,<sup>7</sup> and SCI.<sup>3</sup> It has been used to determine the treatment effect of AFOs on patients with chronic CVA<sup>15</sup> 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).<sup>12-13</sup> 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.<sup>12-13</sup> 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.<sup>7,14</sup>

#### 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.<sup>16</sup> 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.<sup>16</sup> 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).

#### 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.<sup>17</sup>

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)

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
<u>&gt;55</u> Years Old	39.7 ± 17.1

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

Taken from Deathe et al., 05.

Table 6: mEFAP Values for Patients with Chronic CVA, with and	ł
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.

"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 11/2 meter mark and threemeter 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.

K level	AMPnoPRO: Mean + SD	AMPPRO Mean + (SD)
КО-К1	9.7 ± 9.5	25.0 ± 7.4
K2	25.3 ± 7.3	34.7 ± 6.5
К3	31.4 ± 7.4	40.5 ± 3.9
K4	38.5 ± 3.0	44.7 ± 1.8

Taken from Gailey et al., 02.

The mEFAP was originally developed within the stroke population, where it was found to demonstrate good interrater and intrarater reliability and concurrent validity.<sup>17</sup> A later study confirmed these findings, while also reporting good responsiveness to change for the instrument.<sup>18</sup> It has been used to quantify improvements gained during inpatient rehabilitation,<sup>17</sup> to quantify the positive impact of AFOs among chronic CVA patients,<sup>19</sup> (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.<sup>20</sup>

#### 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 (AMP-PRO) 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 article9 or in the third edition of the Atlas of Prosthetics.<sup>21</sup>

The instrument was found to have good interrater and intrarater reliability as well as concurrent validity.<sup>9</sup> 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.

#### **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.<sup>22</sup> 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."<sup>22</sup> 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

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

Table 8: ABC Values for Lower-Limb Amputees

Taken from Miller et al., 03.

of the Amputee.<sup>23</sup> 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.<sup>24</sup> 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 con-

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

Table 9: ABC Values for Coh	ort Populations of CVA Patients
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Taken from + Salbach et al., 06 and \* Botner et al., 05.

fidence.<sup>25</sup> 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 lower-limb amputee population.<sup>26</sup> 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.

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.<sup>27</sup> It received further evaluation within a cohort of patients who had all experienced their CVA within one year of the evaluation.<sup>28</sup> Mean ABC values from these studies are shown in Table 9. Its use has also been reported within the multiple sclerosis<sup>29</sup> and post-polio<sup>30</sup> populations. A copy of the ABC is available online at www.pacificbalancecenter.com/forms/abc scale.pdf

### Pain/Disability

The Socket Comfort Score (SCS) was developed in an attempt to quantify the rather subjective experience of socket discomfort and pain.<sup>31</sup> 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?"<sup>31</sup> 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.<sup>31</sup> The measure has also demonstrated sensitivity to change as socket adjustments and socket replacements aimed at improving comfort resulted in higher SCS values.<sup>31</sup> 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.<sup>32</sup> 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.<sup>32</sup>

#### **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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## The Effect of an Ankle-Foot Orthosis on Gait Parameters of Acute and Chronic Hemiplegic Subjects

2008 Academy Annual Meeting Thranhardt Lecture Series Presentation

 Jason Wening, MS, CP Michael Huskey Daniel Hasso, CPO Alexander Aruin, PhD Noel Rao, MD

#### Introduction

An ankle-foot orthosis (AFO) is often used to assist individuals returning to ambulation after a cerebral vascular accident (CVA). An AFO is designed to provide stability in the sagittal and coronal planes during stance phase, to prevent foot drop during swing phase, and to promote heel strike. Improvements in gait resulting from AFO use have been documented for chronic CVA patients.<sup>1, 2, 3</sup> One study reported gait improvements with an articulated AFO but did not differentiate acute and chronic CVA patients.<sup>4</sup> Gök et al. also reported improvement in gait, recruiting a mix of acute and chronic CVA subjects.<sup>5</sup>

To date, few studies have considered the impact of an AFO on the gait of acute CVA patients or compared the gait of acute CVA patients to chronic CVA patients. The purpose of this study is to compare gait parameters of acute and chronic CVA patients while walking with and without their prescribed AFO. It is hypothesized that the AFO will positively impact gait and that acute patients will ambulate with lower cadence, velocity, and step length than chronic patients.

#### Methodology

Forty subjects with a hemiplegic gait pattern secondary to CVA were recruited from Marianjoy Rehabilitation Hospital, Wheaton, Illinois, with Institutional Review Board (IRB) approval. A convenience sample was recruited consisting of 25 chronic CVA patients (19 men, six women), and 15 acute CVA patients (ten men, five women). Included subjects presented with an Ashworth\* score of less than two. All subjects were prescribed an appropriate AFO for ambulation but were able to ambulate safely without it for ten meters. Data was collected during the CVA clinic at Marianjoy using the GAITRite portable electronic walkway.<sup>6</sup> The order of walking trials, with or without the AFO, was randomly assigned to the subjects. Three trials at self-selected walking speed were collected for each condition. Subjects were allowed to use an assistive device to ambulate if needed. Participants rested between trials and conditions as needed during the experiment. The subjects were not provided extra practice or adaptation time when changing between conditons.

Subject data for velocity, cadence, stride length, and bilateral step length were exported for statistical analysis. A two-way repeated measures ANOVA\* was calculated to test for differences in gait parameters with AFO use as a withinsubject factor, and acute versus chronic as a between-subject factor. Eight of the acute subjects accepted delivery of their first AFO on the day of testing. These subjects were examined independently to determine if the AFO had an immediate impact on gait parameters with no prior experience, training, or therapy. A paired t-test\* was calculated to check for differences in mean gait parameters between the conditions with and without an AFO. An alpha of 0.05 was set as the level for statistical significance.

#### Result

The average age of the 40 subjects was  $62.5 \pm 13.3$  years. The left hemisphere was affected in 23 subjects, and the right hemisphere was affected in 17 subjects. When using the AFO, both the acute ( $0.7 \pm 0.4$  months post CVA) and chronic ( $50.7 \pm 37.5$  months post CVA) groups significantly increased walking velocity, cadence, stride length, and bilateral step length

	Acute w/o	Acute with	Chronic w/o	Chronic with	Sig.
Velocity	35.6	44.5	54.2	61.3	α
(cm/s)	(24.6)	(28.7)	(33.0)	(31.3)	
Cadence	58.2	65.7	74.8	80.0	a, c
(steps/min)	(20.2)	(21.5)	(22.0)	(19.2)	
Stride	67.5	74.7	81.4	87.8	α
Length (cm)	(22.2)	(24.8)	(26.4)	(24.8)	
Sx Step	30.1	33.8	37.7	41.5	a
Length (cm)	(12.8)	(14.9)	(14.9)	(13.0)	
Ox Step	37.4	40.9	43.7	46.3	b
Length (cm)	(12.4)	(11.7)	(13.2)	(12.8)	

 Table 1: Mean and Standard Deviation for Acute and Chronic Subjects' Gait Parameters

 with and without Their AFO

Sx is sound side and Ox orthotic side. (a) Significant difference (p<0.001) between with and without AFO conditions for acute and chronic. (b) Significant difference (p<0.005) between with and without AFO conditions for acute and chronic. (c) Significant difference (p<0.05) between acute and chronic groups.

(Table 1). Velocity in the acute group improved from  $35.6 \pm$ 24.6cm/s to  $44.5 \pm 28.7$  cm/s (p<0.001), while the chronic group improved from  $54.2 \pm 33.0$  cm/s to  $61.3 \pm 31.3$  cm/s (p<0.001). Cadence in the acute group improved from  $58.2 \pm 20.2$  to 65.7 $\pm$  21.5 steps/min (p<0.001), while the chronic group improved from 74.8  $\pm$  22.0 to 80.0  $\pm$  19.2 steps/min (p<0.001). Stride length in the acute group improved from  $67.5 \pm 22.2$  cm to 74.7 $\pm$  24.8cm (p<0.001), while the chronic group improved from  $81.4 \pm 26.4$  to  $87.8 \pm 24.8$  cm (p<0.001). Bilateral step-length parameters improved significantly as well. Acute subjects increased their sound-side step length from  $30.1 \pm 12.8$  cm to 33.8 $\pm$  14.9cm (p<0.001), and chronic subjects increased sound-side step length from  $37.7 \pm 14.9$ cm to  $41.5 \pm 13.0$ cm (p<0.001). Affected-side step length improved from  $37.4 \pm 12.4$  cm to 40.9 $\pm$  11.7cm (p<0.005) in the acute group and from 43.7  $\pm$  13.2 to  $46.3 \pm 12.8$  cm (p<0.005) in the chronic group. There was no significant improvement in step-length symmetry in either group, though. The chronic group walked with a significantly faster cadence than the acute group in both conditions-with and without AFO (p<0.05). Other parameters were not significantly different at the alpha equal 0.05 level between the acute and chronic group.

The subgroup of eight acute subjects using an AFO for the first time made significant improvements in velocity (34.8  $\pm$  11.1cm/s versus 46.9  $\pm$  12.8cm/s; p<0.05) and cadence (53.8  $\pm$  8.9 steps/min vs. 63.0  $\pm$  9.2 steps/min; p<0.005), but improvements in stride length and bilateral step length were not significant.

#### Discussion

The results from this study support the hypothesis that an AFO increases the gait parameters for both chronic and acute subjects with hemiplegic CVA and low tone. These findings concur with the previous research, and gait parameters measured in the chronic group are similar in both mean and standard deviation to previously published works. While most prior works have focused on chronic CVA subjects, or not specified whether their sample was acute or chronic, a comparison was made between acute and chronic subjects. Even though the mean gait parameters for the chronic group were much better than the acute group, the within-group variance and the lack of a paired comparison prevented detection of a statistical difference. This study also demonstrated that an AFO can have a meaningful and immediate impact on the velocity and cadence of acute hemiplegic CVA subjects who have no prior experience or training with an AFO.

The data for this study was collected during an active CVA clinic in a rehabilitation hospital using the GAITRite portable electronic walkway. Most clinics are challenging, hectic settings with little time to waste. This demonstrates that the GAITRite is a reasonable tool for rapidly collecting basic gait parameters in an active clinical setting. The fact that this data was collected in a clinical setting also means that it is subject to the limitations imposed by such a setting. Patients used their prescribed AFO, and no attempt has been made to segregate the data based on type of AFO used.

A deeper, prospective examination of the changes in gait and function that occur as CVA patients recover may be beneficial. While fraught with difficulty, such a study could aid in parsing out the influence of orthotic versus other therapeutic treatments at different times during recovery.

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# The following Thranhardt Lecture Series Finalists will be presenting at the 35<sup>th</sup> Academy Annual Meeting & Scientific Symposium March 4–7, 2009 in Atlanta.

- "Patient Evaluation of an Unloader Knee Brace: A Prospective Cohort Study" Karen Biggs, MBA, MPH
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- "Dynamic Analyses of the Gait of RGO Users"
   W.B. Johnson, MS; Stefania Fatone, PhD, BPO (Hons); Steven Gard, PhD
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he Academy is fortunate to have secured a fifth year of grant funding from the U.S. Department of Education. We intend to make the most of this opportunity in order to provide additional benefits for Academy members, the O&P profession, and the general public. Here's a brief overview of what this year has in store.

#### A Spotlight on O&P Awareness

One of the main goals this year, as in years past, is to use our resources to inform the public about orthotics and prosthetics as a possible career choice. This year, these efforts will include a focus on returning veterans through the development of new career materials, public-service announcements on how to find out more about becoming an O&P provider, and a marketing program that will get our message out to the public in a deliberate and effective way. You can view all of our career materials at www.opcareers.org

We're also taking advantage of opportunities to network with high-school and college students who may be interested in O&P as a future career. We've invited students and residents from across the country to attend the Academy's 35<sup>th</sup> Annual Meeting and Scientific Symposium, March 4–7, 2009, in Atlanta, Georgia. There will be numerous opportunities for networking and exposure to O&P professionals and technology during the four-day meeting, with specific sessions and events designed just for students and educators. Get all the program details online at www.academyannualmeeting.org/2009

#### The Best in Research

This year, the Academy will conduct its ninth State of the Science Conference (SSC). The topic selected is Upper-Limb Prosthetic Outcome Measures. Look for the results to be published in the third quarter of 2009. During these single-subjectarea conferences, experts rank all of the available literature on a subject and summarize it. They then determine what is known on the subject from the current literature and develop a series of questions that must be answered through additional research in order to prove the efficacy of the services O&P practitioners provide. The proceedings from the previous SSCs are available on our website at www.oandp.org/jpo/ssc

#### More Online Learning Opportunities

In addition to our One-Day Seminars, the Paul E. Leimkuehler Online Learning Center (OLC), *Journal of Prosthetics* & *Orthotics (JPO)* article quizzes, and all of the education opportunities you expect at the annual meeting, we'll also be working to turn the results of the SSCs into learning opportunities. We know how much you rely on the Academy for your continuing education needs, and we're proud to offer you the best learning opportunities in the O&P profession.

#### **Evidence-Based Practice**

The grant will enable the experts who helped develop the certificate program on evidence-based practice to present this program at a number of Academy chapter meetings. The Academy's goal is to make this information available to as wide an audience as possible, and this is another step in that direction. Of course, you can also take this course online through the Paul E. Leimkuehler OLC and earn up to five continuing education credits. Complete all six modules of the online course, and you'll earn a Certificate for Professional Development, which counts toward becoming designated a Fellow of the Academy. Visit www.oandp.org/olc/evidence\_based\_practice for details.

#### Improved Training for Residency Directors

This year, the Academy will fund a National Commission on Orthotic & Prosthetic Education (NCOPE) project to develop online education modules for residency directors and faculty members involved with supervising and teaching residents. Topics will include objective writing, assessment methods, evaluating the complexity of tasks, performance assessment/ outcomes, and providing feedback.

In improving the training provided to residency directors, NCOPE hopes to improve the learning experience for orthotic and prosthetic residents. This will in turn make them better prepared for their American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) certification exam, and make them better practitioners.

#### For the Good of All

All of these initiatives are undertaken with one key goal in mind: to improve the field of orthotics and prosthetics. From evidence-based practice and other research to more highquality continuing education offerings for practitioners, to improving the experience residents have while in training, to exposing high-school students to O&P as a possible career choice, we're working hard to ensure the future of your chosen profession.

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