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Activity Monitor Accuracy for Lower-Limb Amputees Living in Colombia and Texas

Gary Guerra Briseno

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LOMA LINDA UNIVERSITY School of Allied Health Professions in conjunction with the Faculty of Graduate Studies

Activity Monitor Accuracy for Lower-Limb Amputees Living in Colombia and Texas

by

Gary Guerra Briseno

A Dissertation submitted in partial satisfaction of the requirements for the degree Doctor of Philosophy in Rehabilitation Science

June 2017

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Each person whose signature appears below certifies that this dissertation in his opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Philosophy.

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Activity Monitor Accuracy for Lower-Limb Amputees Living in Colombia and Texas

by

Gary Guerra Briseno

Doctor of Philosophy, Graduate Program in Rehabilitation Science Loma Linda University, June 2017 Dr. Grenith Zimmerman, Chairperson

Maintaining physical activity for lower limb prosthesis wearers is important in order to reduce comorbidities and decrease physical function. Activity monitors can provide motivation for the wearer and outcome measurements for the health care professional. Two cohorts of lower extremity amputees participated in two separate studies examining the accuracy of activity monitors. Each participant completed a 200m walking trial while activity monitors were fitted to them and step counts were compared with actual counts. For participants walking on even ground in a developing setting no significant differences between pedometer and actual counts were found, nor were there significant differences with pedometers placed at various locations on the body. In both developed and developing settings on even and uneven terrain, percentage errors were greatest with the pedometer on the neck strap and least at the hip. For individuals walking on uneven ground, no significant differences between actual counts and activity monitor counts were found. The Omron HJ-329 pedometer is a reliable activity monitor for persons living in developed and developing countries.

CHAPTER ONE

INTRODUCTION

Activity monitoring and lower limb prosthetics are two fields that have a synonymous relationship with each other. The primary outcome of lower limb prosthetics is a mobility and functional independence. At the core of activity monitoring is the measurement of mobility, acute or prolonged activity. These two fields each make vital contributions to one another. The lower limb prosthesis user is encouraged to become physically active by the prosthetist who creates a customized lower limb prosthesis for their ambulation. Physically activity is important as it directly relates to the quality of life of the individual and can reduce susceptibility to co-morbidities. Therefore, monitoring the activity of these individuals is of great interest to prosthetist, researchers, health care professionals and the patient.

Identifying viable methods for measuring activity in both laboratory and free living settings has received increased interest in the health care community. Furthermore, as activity monitoring should be as non-invasive and user friendly as possibly, making activity monitor device placement location user defined is an advantage. There is a dearth of literature examining the accuracy of these monitors in the lower limb prosthesis user population. Yet still, there is an increasing number of persons with disabilities throughout the globe. In this same vein, organizations such as the World Health Organization (WHO) has advocated the design and development of low cost technologies to assist in the rehabilitation of persons with disabilities. Making activity monitoring affordable, reliable and user friendly are all imperative goals for the lower limb prosthesis user. There are several methods of measuring activity, subjective and objective methods can

both be used and provide very unique pictures of a person's activity level. There are strengths and weaknesses to both methods but identifying a single measurement technique which is feasible to implement into a modern busy practice is imperative. A thorough review of literature will provide a deeper insight into why and how activity monitoring and prosthetics are so important to each other.

Literature Review

Measurement of Physical Activity

Physical activity (PA) is defined as the movement of the body by the skeletal muscles that produces energy expenditure, and that can be performed in many different ways and at various intensities.¹ Physical inactivity is a major cause of chronic disease and disability.² The simple act of regular and regimented walking provides children and adults a means of beneficial exercise of the cardiovascular system.^{3,4} There is literature evidencing the benefits of physical activity for able-bodied individuals,⁵ as well as for individuals with metabolic diseases.⁶ Comorbidities can also be reduced with adequate amounts of regular exercise.⁷ Furthermore, physical activity is also an important health related component for persons with disabilities (PWD).⁸ There is some literature examining the effects of physical activity and exercise for individuals with lower limb amputations, 9 as well as research identifying reliable methods for measuring PA in these individuals.¹⁰

Mobility, functional independence, and a return to habitual physical activity are all core tenants of orthotic and prosthetic rehabilitation. In fact, for the lower-extremity amputee (LEA), mobility is one the most sought after rehabilitation goals.¹¹ Therefore,

prosthetic clinical practice has focused on making certain that LEA are provided with interventions that will result in functional independence. The combined efforts of the prosthetist and a motivated user can markedly improve health related quality of life (HRQoL) of the prosthesis wearer. Outcomes such as HRQoL and PA are important because they serve as a barometer for the rehabilitation team to gauge effectiveness of interventions.¹²

Quantification of activity has been an important advancement in the evaluation of activities in movement science and health promotion.¹³ Measuring human movement whether it is walking, running, skipping or hopping are all important in order to provide structured physical activity recommendations. Walking measurements provide insight into, an individual's activity level. When step activity is matched to age, an individual can be compared to normative step count data. In doing so, the individual can gauge their PA level relative to their suggested activity levels. The benefit of step count data is that an individual's data can be used as a reference point for health behavior change. Physical activity can be measured using subjective self-report instruments or objective activity monitoring devices. Both methods rely on an individual's compliance, but only one requires the person to speak, write, and recall activity bouts. We will first review these subjective instruments along with their benefits and criticisms and later review objective PA monitoring devices.

Subjective Instruments

The simplest and oldest method of determining PA levels is through the use of a subjective self-report instrument. Self-report instruments such as questionnaires or

surveys rely on an individual's ability to recall PA during a previous period of time. One of the most widely used self-report instruments for measuring PA is the International Physical Activity Questionnaire (IPAQ).¹⁴ It has been tested for validity and reliability in children and adolescents'¹⁵ and adults and older adults.¹⁶ For this instrument, the individual is required to recall PA and then record that information into the survey. This method of recording PA is a classic example of subjective self-reporting methods. The IPAQ has also been used to measure PA of persons with Type 2 diabetes and PWD.^{17,18} The use of this instrument in disease related populations further emphasizes the importance of measuring PA in PWD, however, the reliability of the instrument in rural settings is less than in urban settings. There are benefits of measuring multiple domains of activity in the IPAQ, especially for developing settings, but this tends to give higher values of PA which might not elucidate the amount of actual PA an individual is doing.¹⁹ Persons with LEA are often unable to maintain a level of activity necessary for prevention of further disability or disease.²⁰ Therefore, collecting actual activity levels of this population is critical in order to direct physical activity and health promotion interventions, something the IPAQ would not be capable of determining.

Subjective Instruments for Lower Extremity Amputees

The IPAQ has been used to evaluate the PA and its role on the quality of life of amputees living in developing settings.²¹ The study with Da Silva and colleagues provided a small number of amputee participants with the IPAQ questionnaire and found no link between a higher activity level and overall quality of life. They did observe a link between increased PA and psychological domains of quality of life for participants.²¹

This research was not without its limitations, the number of participants and limited prior investigations examining PA and quality of life in amputees limited the generalizability of this work. The Houghton Scale which evaluates prosthesis use can also provide subjective activity data for persons wearing prosthesis.²² This scale is great in that it focuses solely on usage of an individual's prosthesis device. This outcome alone is meaningful for a prosthetist needing to assess prosthesis use, however, the scale is not able to discriminate between unilateral and bilateral amputations and isn't able to provide information on how, and to what extent, the prosthesis improves quality of life.²³

Still, the amputee population can indeed benefit from self-report instruments designed to measure PA. A few instruments have been designed to determine PA levels in LEA. The Prosthesis Evaluation Questionnaire $(PEQ)^{24}$ and the Orthotic and Prosthetic User Survey($OPUS$)²⁵ are both self-report instruments that can be administered by the prosthetist or rehabilitation team, and have both been deemed valid and reliable indicators of PA in this population.^{26,27} The usefulness of the PEQ was evidenced in research designed to compare a non-microprocessor and microprocessor knee. These authors were able to utilize the PEQ to support improvements in other outcome measures of the study. 28

The OPUS questionnaire has been linguistically and culturally adapted to fine tune its measurement properties to the Swedish population.²⁹ This study supports the importance of PA and functional outcomes on a global scale for LEA. This is especially important since there is growing evidence that obesity is becoming a global epidemic, with some describing this trend using the term 'globesity'.³⁰ Persons with lower limb prosthesis may be a smaller portion of society, still there are estimates of nearly 2 million

people living in the US with a limb amputation.³¹ Quantification of PA levels in this population is an outcome measure, not only for the prosthetist or rehabilitation team, but also the user. Activity as an outcome measure is a barometer for a patients overall health and quality of life. In addition, simplifying and streamlining collection of amputee PA data is critical for compliance and time management of patient visits.

A few issues arise with the use of self-report instruments of physical activity. A recent publication further emphasized the importance of utility of outcome measures in clinical practice by investigating the practitioner compliance and feedback of an outcome measure protocol.³² They reported some difficulties in time management and compliance of recording of outcomes data. This is no surprise, as finding time to administer a questionnaire during a 30 minute to one hour prosthesis fitting is difficult. Moreover, the recall ability of individuals during self-reporting has been questioned.³³ Often times persons are asked to recall physical activity from the past, which requires the ability to remember precise bouts, durations and intensities of PA from weeks to months prior. Questionnaires might also be limited by the method they are delivered to the individual. Self-report instruments can in theory be performed during a clinic visit, but if this is not possible, then the instrument must be mailed to the patient. Questionnaire research provides some evidence to indicate a lowered response rate for longer surveys,³⁴ potentially limiting the amount of information which can be obtained. Most importantly, subjective measures do not reveal the free-living day to day changes in human movement.³⁵ Obtaining continuous outcome measures should be encouraged and therefore posits the need to record physical activity data that does not require patient recall nor the need to fill out paperwork. We will now review physical activity

monitoring devices.

Activity Monitors

The hallmark of activity monitoring is actual physical activity measurement through use of objective data driven activity monitors. Activity monitors have been a valuable asset to health promotion advocates, researchers and exercise advocates for many years. The simplest and most objective measure of human movement is step count recording through use of a pedometer. The traditional pedometer is a body-worn device which contains a spring-levered mechanism that moves during walking and registers these vertical movements as steps.¹ The modern pedometer is centered around a piezoelectric pedometer that senses vertical accelerations of the hip to register step counts.³⁶ This form of pedometer has been shown to provide more accurate measures of step activity than spring-levered counters.^{36,37} The strength of a pedometer depends on its reliability in measuring step counts per the user. As previously mentioned, there are a number of populations which can benefit from activity monitoring. Pedometers have been tested for accuracy of measurement and have achieved acceptable reliability in children, $38,39$ adults⁴⁰ and the elderly.⁴¹ Furthermore, accurate pedometers have been discovered for persons with disabilities.^{37,42} One might postulate that if an activity monitor can provide an accurate step count in one group of individuals that the device might be accurate in a different population. This unfortunately is not true since the accuracy of pedometers tends to degrade when users walk at slower speeds and with irregular shuffling gait, 43 a very real possibility for LEA. 44

Thus, it is important for activity monitor accuracy testing to occur for all persons

including persons wearing lower limb prosthesis. Some pedometers and the tri-axial accelerometer have been tested for accuracy in the LEA.^{10,45} The accelerometer can detect motion beyond that of vertical accelerations of the hip and provide change of velocity measurements.⁴⁶ The utility of accelerometers for LEA is in their ability to provide cadence and intensity of walking bouts. This is a metric that practitioners can use for determination of activity level, a practice that is critical in today's K-Level driven prosthesis practice. One device that has been routinely used in numerous research publications is the StepWatch (Modus Health, Washington D.C). More recently an updated version, the StepWatch 3 was released and was recently utilized for long-term amputee data collection research.²⁰ Still, it is important to note that higher end devices such as the StepWatch 3 are also higher priced than pedometers. The pedometers of today still offer the simplest and most meaningful of all step derived metrics, i.e. step count. We previously tested the accuracy of one pedometer model called the Omron-HJ321 (Omron Healthcare, Japan) in LEA.⁴⁵ Actual step counts were compared with three research grade pedometer models from three different manufacturers. This pedometer provided percentages of error less than 3%, which is an established acceptable percentage of error,⁴⁷ however, the spring levered pedometers in our study were unable to register step counts as well as the piezoelectric pedometer. This finding is consistent with previous piezoelectric pedometer research showing more accurate step counts at higher speeds of walking.⁴⁸ The pedometer is not without its limitations, nor is the accelerometer. One study evaluated the accuracy of three types of pedometers in community dwelling adults at cadences of 50 steps per minute, 66 steps per minute, 80 steps per minute as well as a comfortable walking speed. They too discovered that the

pedometers were less accurate at slower walking speeds.⁴⁹ A study investigating the accuracy of six tri-axial and one uni-axial accelerometer reported that the placement location of the device had an effect on reliability of activity measurements, however, these researchers observed more accurate measurements during outdoor walks as compared to indoor walks. They postulated that a need to start, stop, and turn around at designated indoor markers might have caused differences in activity counts.⁴⁸ Furthermore, it is important to note that prosthesis wearers tend to walk at a slower selfselected walking speed than able-bodied individuals.⁵⁰ This well-known feature of amputee walking must be considered by activity monitor manufacturers when designing a device and the corresponding step calculation algorithms. It is important to use monitors which can provide reliable and economically attainable metrics in light of the aforementioned issues with LEA gait.

Reducing error by placing the pedometer in a specified location is also essential because traditionally the pedometer is most accurate when placed at the anterior midline of the thigh using a pedometer belt. The necessity to wear a pedometer belt or clip the pedometer on a pant waist line might not be as acceptable as a wrist worn monitor, pocket monitor or even neck monitor. Future investigations must consider making the activity monitors user friendly, yet still accurate. Pedometers and accelerometers which are accurate for LEA have been identified, yet, there are still special populations and environmental considerations that must be considered when measuring objective step counts for LEA.

Environmental Considerations for Measuring PA of LEA

A person wearing a lower limb prosthesis typically participates in a wide range of activities that take place in a variety of outdoor environments.⁵¹ The terrain an amputee walks on also changes from day to day, especially for persons in developing nations where smooth surfaces might not always be prevalent.⁵² Uneven ground has a marked effect on the biomechanics and physiological responses of a LEA.⁵³ Differences in stride times have been observed in prosthesis wearers and it is suggested that these temporal spatial changes occur as a result of amputees needing to reduce variability of movement of the center of mass (CoM) ⁵⁴ LEAs suffer from lateral instability, and therefore are unable to control their residual limb abduction and adduction movements.⁵⁵ Walking on uneven terrain depends on elastic properties of ligamentous and tendinous structures of the limb,⁵⁶ structures which are not available to the LEA. Therefore, amputees must depend on the mechanisms within their prosthetic foot or knee to provide sufficient support. Unfortunately, there is a paucity of concrete data examining step activity of LEA in developing nations. Some activity monitor research has investigated activity count differences while traversing on different terrains, but this research was performed with able-bodied persons.⁵⁷

Purpose

A breadth of literature has been conducted testing the accuracy of activity monitors in controlled and smooth surfaced environments, however, to the authors knowledge, there is little research investigating the accuracy of these monitors. To this end, the primary objective of this research was to evaluate the accuracy of various

pedometer placement locations while walking in developed and resource-limited settings using the Omron HJ-329 pedometer for LEA.

CHAPTER TWO

THE ACCURACY OF THE OMRON HJ-329 PEDOMETER FOR LOWER LIMB AMPUTEES LIVING IN COLOMBIA

Abstract

There is a need to identify reliable and affordable activity monitors for the lower limb amputee population living in developing countries. The objective of this study was to assess the accuracy of the Omron HJ-329 Pedometer worn at various locations for lower-limb prosthesis wearers residing in Colombia. Nineteen participants were fitted with the Omron HJ-329 Pedometer at the right anterior superior iliac spine, left anterior superior iliac spine, right hip, left hip, right pocket and left pocket, as well as a pedometer on a neck lanyard situated on the chest. Participants walked on a 200m walkway at a selfselected pace while actual step counts were recorded. Repeated-measures (RM) analysis of variance (ANOVA) showed no significant difference between actual counts (ACs) and any of the pedometer counts. Percentage errors were greatest with the pedometer on the neck strap (7.1%) and the left pocket (7.0%) followed by right pocket (5.8%), left hip (1.8%) and right hip (2.4%). The Omron HJ-329 Pedometer is an accurate and affordable activity monitor for lower-limb prosthesis wearers living in developing countries.

Background

In Colombia between the years of 1990 and September 2014, there were 10,847 victims of unexploded ordinances; 8,659 people had life-altering injuries and 2,188 people were killed. Antipersonnel mines affect people while they are participating in a variety of activities of daily living. The number of these incidents has declined in recent years from 368 incidents in 2013 to 222 in 2015.¹ Limb loss has the capacity to hamper an individual's ability to live independently and participate in a variety of activities of daily living such as working and providing food and shelter for themselves and their family.² An amputee who continues to live a sedentary lifestyle will most likely have an increase in health related issues.³ A sedentary lifestyle increases the risk of developing cardiovascular disease and other chronic diseases such as obesity,⁴ which is a risk factor for type 2 diabetes.⁵ Unfortunately, persons with amputations have a higher risk for mortality from cardiovascular disease than their non-amputee peers,⁶ and in order to reduce the risks of developing cardiovascular disease, persons with amputations must maintain an active lifestyle.⁷ A recent review of the literature provided strong evidence of the wide range of health benefits that physical activity offers.⁸ The benefits of physical activity are not solely preventive, in fact, an individual who lives a more active lifestyle can achieve increased physical function,⁹ and a higher quality of life.^{10,11}

With an increasing prevalence of metabolic diseases resulting from inactivity, the need to identify accurate physical activity monitors has become progressively more important.¹² Questionnaires and surveys rely on an individual's ability to recall activity but may not be accurate representations of daily physical activity,¹³ and the ability of questionnaires to give objective measures of activity is also debatable.¹⁴ Using objective

activity monitors such as pedometers to measure amputee activity is preferred because self-report methods have been shown to be less accurate for measuring actual activity in this population.¹⁵ Pedometers are inexpensive, accurate, reliable and provide important measures of ambulant activity such as step count and distance walked over short and longer durations.¹⁶ Newer pedometers utilize a piezoelectric sensor to measure steps and distance in the vertical plane, $17,18$ and have been regarded as valid tools for measuring physical activity.¹⁹ Measuring amputee activity in developing countries requires the use of an affordable, reliable, and robust activity monitor. Using an accurate and economical pedometer to measure amputee prosthetic activity can give clinicians, researchers, funding agencies, and amputees important outcome measures on activity levels.²⁰ Unfortunately, limited research tracking amputee activity in Colombia exists.²¹ This may be as a result of the unavailability of economical and accurate tools to measure amputee activity. The recommended mounting location for pedometers is at the anterior midline of the hip, and in the past, wider abdominal circumferences have had an effect on pedometer accuracy.²² Currently, there is no data on the validity and reliability of the HJ-329 pedometer worn at different positions in individuals wearing a lower-limb prosthesis. An ability to modify the suggested wearing position can increase potential use and acceptability of a pedometer, yet there is a limited amount of literature examining the accuracy of pedometers worn in non-traditional wearing positions such as the pocket, or around the neck.²³ The objective of this study was to evaluate the accuracy of a new version of a pedometer, the Omron HJ-329 (Omron Healthcare, Inc. Lake Forrest, IL, USA) for lower limb prosthetic wearers living in Colombia, as well as to investigate the accuracy of the HJ-329 pedometer while worn in various locations.

Methods

Participants

All participants were recruited from the Laboratorio Gilette O&P clinic located in Bogota, Colombia. The study was approved by the Institutional Review Board (IRB) of Loma Linda University. Individuals who volunteered for the study met the following inclusion criteria: lower limb amputees with a healthy residual limb, between 18 to 65 years old and at least six months post-amputation. Individuals who were pregnant were excluded. Interested individuals signed an approved IRB consent form. A total of 19 lower-extremity prosthesis wearing participants took part in this study. They had a comfortable and functioning final prosthesis and were capable of walking unassisted without the use of a cane, walker, or other assistive device for 200m.

Procedures

Participant height and weight data with prosthesis and shoes on were collected using the SECA S-214 portable height rod (Hanover, MD, USA) and the DR400C digital body weight scale (Webb City, MO, USA). Demographics of study participants were collected as well. Prior to data collection, the Omron HJ-329 pedometer batteries were replaced with new batteries and fit to the investigator at the anterior midline of the hips. The investigator walked 100 steps while counting actual hand-tallied counts to check for accuracy of all devices. If the device registered a margin of error of greater than 3% (3 steps out of 100), which is the recommended maximum permissible rate of step miscount, $24,25$ the pedometer was not used. This procedure occurred until a properly functioning pedometer without the above mentioned error was confirmed.

The participants were fitted with a Velcro Walk4Life pedometer belt (Walk4Life Inc., Plainfield, IL, USA) on the waistline of the hip, an Omron HJ-329 piezoelectric pedometer was fitted at the anterior midline of both left and right thighs, in left and right pockets and around the neck using a neck strap. On level ground, a straight 100m indoor path was marked using a measuring wheel. An orange cone was placed at the end of the path that served as the turning point for participants. Once the pedometers were fitted to the participant, the participant was asked to move to the starting line and the pedometers were reset to zero. The participant was then instructed to walk to the cone, turn around, and walk back to the start line at his/her normal self-selected pace. The investigator counted each step using a hand tally counter (Model no.77; Lab Safety Supply Inc., Janesville, WI, USA), which served as the criterion measure of actual step counts. Upon completion of the walk, participants were instructed to cease motion while pedometer and hand tally counts were recorded.

Statistical Analysis

Mean and standard deviation (SD) of pedometer counts compared to hand-tallied counts were determined. Repeated-measures (RM) analyses of variance (ANOVAs) were used to test for differences between pedometers and actual counts (ACs) obtained while walking, with α set at 0.05. Post-hoc comparisons were explored using the Bonferroni technique to control for type I error rate. A single measure intraclass correlation coefficient (ICC) from a two-way random effects ANOVA was used to assess the agreement between AC and pedometer counts, with 0.90 or greater considered high agreement, 0.80 to 0.89 moderate agreement, and 0.79 or lower low agreement.²⁶ Bland-

Altman plots of actual counts compared to pedometer counts provided an indication of any overrepresentation or underrepresentation of steps as well as agreement between measures.²⁷ If error scores were 0, this indicated no differences between actual steps taken and steps registered by the pedometer. Percentage error was calculated as ([steps detected by pedometer - AC/AC) x 100. All statistical tests were performed using IBM SPSS Statistics Software version 20 for Windows (Chicago, IL, USA).

Results

Participant characteristics can be seen in Table 1. The mean and SD values for the AC and pedometer counts are provided in (Table 2). The Greenhouse-Geisser correction was used to determine the significance for walking $(F_{2.59,22.0} = .651, p = .57)$ because the Mauchly test statistic was significant ($p < .001$). We found no significant interaction, so a main effects for amputee side and location was explored. There was no significant main effect between amputee side when pedometer location was combined ($F_{2,17} = .262$, p = .77), nor was there a significant main effect of pedometer location when amputee side was combined (Pillai's Trace = .30, $F = 1.101$, $df = (5.13)$, $p = .41$), which indicated no significant differences between any of the locations. Pairwise comparisons using Bonferroni post-hoc tests also indicated no significant differences in step counts compared to actual counts for any of the classifications and locations $(p > 0.5)$. Wearing the pedometer on the hip had highest agreement, which is consistent with previous literature.²⁸

The greatest ICCs and lowest error were observed in the pedometers located at the right and left hip locations (Table 3). Percentage errors were greatest with the pedometer

on the neck strap (7.1%) and the left pocket (7.0%), followed by the right pocket (5.8%), right hip (2.4%) and left hip (1.8%). For the difference between the means, Cohen's d effect size values were as follows: actual count and neck strap (*d*= 0.40), actual count and right pocket (*d*= 0.35), actual count and left pocket (*d*= 0.36), actual count and right hip $(d= 0.19)$, actual count and left hip $(d=0.15)$. Bland-Altman plots demonstrated mean error amongst the pedometers, and the tighter limit of agreement visible with the left hip pedometer compared with the other pedometer locations (Figure 1).

	Total $(N = 19)$	Male $(n = 14)$	Female $(n = 5)$
Age, y	33.2 (12.6)	31.0(11.6)	39.4 (14.5)
Height, cm	167.5(10.0)	169.6 (9.3)	160.92(9.7)
Weight, kg	70.5(13.9)	68.7 (12.1)	76.1 (18.7)
BMI, kg/m^2	25.1(4.8)	23.8(3.7)	27.9 (7.4)
Classification (n)			
Right transtibial	3	$\overline{2}$	1
Left transtibial	7	5	$\overline{2}$
Right transfemoral	3	$\overline{2}$	
Left transfemoral	3	3	Ω
Knee disarticulate			θ
Bilateral transtibial	1	0	
Bilateral transfemoral	1	1	0
Reason for prosthesis (n)			
Trauma	13	9	$\overline{4}$
Illness	$\overline{2}$		1
Congenital	4	4	0

Table 1. Mean (SD) of Participant Characteristics of Lower-Limb Amputees in Colombia by Gender.

¹BMI: body mass index

2 Illness: cancers, diabetes type 2, vascular disease

	Mean (SD)	Effect size
Counts		
Actual counts	282.9 (30.7)	
Omron HJ-329 Neck strap	302.8 (48.4)	0.40
Omron HJ-329 Right pocket	299.3(40.8)	0.35
Omron HJ-329 Left pocket	302.8(57.0)	0.36
Omron HJ-329 Right hip	289.5(20.4)	0.19
Omron HJ-329 Left hip	288.0 (13.9)	0.15

Table 2. Mean (SD) and Effect Size (Cohen's d) of Counts Registered During a 200-m Walk in Prosthesis Wearers in Colombia.

Table 3. Intraclass Correlation Coefficients Between Actual Counts and Pedometer Counts During Walking in Colombia (95% confidence interval).

	$ICC* (95%CI)$	
Omron HJ-329 Neck strap	$.68$ (.19 to .87)	
Omron HJ-329 Right pocket	$.76(.38 \text{ to } .90)$	
Omron HJ-329 Left pocket	$.63$ (.05 to .85)	
Omron HJ-329 Right hip	$.91$ (.76 to .96)	
Omron HJ-329 Left hip	.95 (.88 to .98)	

*ICC, intraclass correlation coefficient

(Actual + Right Pocket)/2 (steps)

Figure 1. Bland Altman Plots for Pedometer and Actual Counts for Each Pedometer Location in Colombia.

Discussion

The primary objective of this study was to examine the ability of the Omron HJ-329 to accurately measure amputee activity of individuals with lower limb amputations. The second objective was to determine the most accurate pedometer placement location on the body. Previous literature identified 3% pedometer error as an acceptable error reading.²⁴ The pedometers in the current study had a wide range of errors. The least amount of error was seen in the pedometer located at the left hip (1.8%) followed by the right hip (2.4%), right pocket (5.8%), left pocket (7.1%) and the neck strap location (7.0%). Pairwise comparisons were explored and while there were trends for greater accuracy when worn on the opposite side of the affected leg, there were still no significance differences. There were no significant differences between the various placement locations and actual counts. These findings are encouraging, because they allow the amputee to place the pedometer at any location they desire. If the individual can't wear the pedometer on one side, then they can wear it on the opposite side. In addition, they can choose to wear the pedometer at any of locations explored in this study.

The cost of the pedometer we used is approximately \$30 USD. Other activity monitors that provide step activity data such as the Fitbit (San Francisco, CA, USA) cost approximately \$75 USD but might not be appropriate as a clinical tool. Excellent amputee activity monitors such as the Modus Health Step-Watch™ (Washington, DC, USA), offer a number of additional metrics for the prosthetist to use as an outcome measure tool.²⁹ The cost of this particular device is approximately \$1995 USD. In Colombia, the ability to accurately track an amputee walking with an affordable device is

essential, however, a potential advantage of a consumer wrist-worn activity monitor is its ability to be worn on a user's wrist, hereby removing the necessity of continually placing the monitor on and off the body. Pedometers are still most accurate when worn at the waist or pocket. Future research should investigate compliance between wrist and waist worn activity monitors.

A limitation of this current study is that data collection was conducted in a controlled indoor setting during a short 200m trial. Future studies should examine both short-term activity and volume of activity monitoring via pedometers in lower-limb amputees in a variety of terrains, as well as explore amputee activity in free-living conditions. Another limitation of the current study was that the vast majority of our participants lost their limbs as a result of trauma. The results of this study may not be generalizable to individuals who have lost their limbs due to other causes.

In Colombia, years of conflict and use of unexploded ordinances has led to a high number of casualties and limb amputations. The government in Colombia has taken steps to prevent future limb amputations by instituting nationwide demining as well as making sure that individuals who become amputees as a result of the conflicts receive prosthetic treatment. Attempts must be made to motivate these amputees to return to physical activities they once had. Activity monitors can provide a means to motivate and engage individuals to participate in physical activity.³⁰ Pedometers and wearables are becoming increasingly popular with able-bodied individuals in developed nations. The same should be true for prosthesis wearers in both developing and developed countries. It is reasonable to say that the Omron HJ-329 pedometer can be used to track basic ambulant

activity with confidence in individuals with lower limb amputations residing in developing countries.

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CHAPTER THREE

THE ACCURACY OF THE OMRON HJ-329 PEDOMETER FOR LOWER LIMB AMPUTEES LIVING IN TEXAS

Abstract

Pedometer location reliability and free-living uneven terrain accuracy must be explored as valuable outcome measurement metrics for lower extremity amputees and is cornerstone to evidence-based practice. The objective of this study was to assess the accuracy of the Omron HJ-329 Pedometer worn at various locations for lower-limb prosthesis wearers residing in Texas. Ten participants were fitted with the Omron HJ-329 Pedometer at the right anterior superior iliac spine, left anterior superior iliac spine, right hip, left hip, right pocket, and left pocket, as well as a pedometer fitted around the neck with a lanyard. Participants walked on smooth and uneven ground for 200m at a selfselected speed while actual step counts were recorded. On smooth ground, there was no significant difference between actual counts (ACs) and the counts from the left hip pedometer readings only. In addition, there were no significant differences-between actual counts and any of the pedometer counts during the uneven ground walking trial. Percentage errors were greater for pedometers on the neck strap and less for pedometers worn at the hips and pockets. The Omron HJ-329 Pedometer is an accurate and affordable activity monitor for lower-limb prosthesis wearers walking in free-living environments.

Background

Outcome measures in the field of orthotics and prosthetics (O&P) have been encouraged by O&P researchers and the field as a whole,^{1,2} and in some countries such as the US, they have become part of a clinical practice. There are multiple methods available for evaluating use and effectiveness of various prosthetic and orthotic interventions. Some subjective methods are self-report measures which provide a better insight into user satisfaction, 3 device use, psychosocial aspects, and health-related quality of life.^{4,5} These instruments provide both rehabilitation professionals and reimbursement agencies a systematic method of getting important user feedback on interventions. Physical activity (PA) is an important outcome to measure because of the notable contribution that mobility and activity have on an lower extremity amputees (LEA) life.⁶ Lowered comorbidities, increased physical function and quality of life are just a few benefits of PA for the LEA.⁷

Self-report physical activity measures have been developed for persons with disabilities and a few instruments have been used in the prosthesis wearing community.^{8,9} The utility of these patient reported outcomes is that they are swift to implement and noninvasive, however, their reliability has been questioned, as a person's ability to recall measures such as physical activity is sometimes unreliable.¹⁰ Objective and quantitatively driven outcome measurement tools offer what self-report measures cannot, i.e. the ability to truly measure physical activity.¹¹ Inexpensive pedometers have been utilized for tracking PA of individuals with varying disabilities,¹² as well as able-bodied persons.¹³ Although the data collected is simply step counts, it is step count that can provide a reliable indicator of how active an individual is^{14} during short¹⁵ and even longer

durations.¹⁶

Step counts for LEA have been reported before as roughly 4,217 and 2,800 steps per day respectively, $17,18$ however, another study found lower average step counts of 1,540.¹⁹ More recently, the advent of wearable technology and wrist-worn pedometers has provided an easier entry for users to comply with PA monitoring. Although, as of yet, the accuracy of values obtained from some of the wrist-worn monitors is still questionable,²⁰ especially in free-living environments.²¹

In order for wearable technologies and traditional pedometers to be adopted for use by the prosthesis wearing community, they must be accurate. Our previous research identified accurate and reliable body-worn pedometers for the amputee users.²² Still, prosthesis wearers must traverse on a variety of terrains during their daily routine. The ability to ambulate on smooth and uneven surfaces is not an occasional event for an amputee; it is a potentially daily occurrence. Modern pedometers employ the use of piezoelectric sensors to sense vertical accelerations of the hip.²³ Slower walking tends to provide less accurate measurements, 23 and this could further be exacerbated by varying surface heights. Uneven surfaced walking has had a marked effect on gait for both ablebodied and LEA persons. 24.25 Therefore, activity monitors should be capable of providing accurate measurements of walking activity during uneven terrain. There has been limited research investigating the accuracy of activity monitors on even and uneven terrain in prosthesis wearers. Although research has tested the accuracy of amputee activity monitors, the tests were conducted in laboratory and smooth surface settings.²² An activity monitor that provides accurate measurements on free-living terrain could be used as a reliable outcome measurement tool for prosthetists. To this end, the objective of this

study was to determine the accuracy of the Omron HJ-329 pedometer in prosthesis wearers walking on even and uneven surfaces.

Methods

Participants

The study was approved by the Institutional Review Board (IRB) of Loma Linda University. Participants were recruited from prosthetic clinics and prior to participation signed an approved IRB consent form. Participants were lower limb amputees with a healthy residual limb, ages 18-65 years and at least six months post-surgery. They all had comfortable and functioning final prostheses, and were capable of walking unassisted without the use of a cane, walker, or other assistive device for 200m two times. Ten lower extremity prosthesis wearing participants (male n=8, female n=2) participated in this study.

Procedures

Participant height and weight data with prosthesis and shoes on was collected using a SECA S-214 portable height rod (Hanover, MD, USA) and the DR400C digital body weight scale (Webb City, MO, USA). Participant demographics such as amputation cause and prosthesis type were also collected. Prior to data collection, the pedometer batteries were replaced with new batteries and fitted to the investigator. The investigator walked 100 steps while counting actual hand tallied counts to insure accuracy of all devices. If the devices registered a margin of error of greater than 3% (3 steps out of 100), which is the recommended maximum permissible rate of step miscount, the

pedometer was not used.26,27 An Omron HJ-329 piezoelectric pedometer was placed in both the left and right pocket, around the neck via a neck strap and on the right and left hip of the study participant.

Walking Trials

On both level ground and uneven ground, straight 100m paths were marked using a measuring wheel and an orange cone placed at the end of the guided path which served as a final returning point for participants. Once the pedometers were fit to the participant, the participant was moved to the starting line and the pedometer was reset to zero. The participant then was instructed to walk to the cone, then turn around and walk back to the start line, at his/her normal self-selected walking pace. The investigator counted each step using a hand tally counter (Model no.77; Lab Safety Supply Inc., Janesville, WI), which served as the criterion measure of actual step counts. Upon completion of the walk, participants were instructed to cease motion while pedometer counts were collected. After completion of the even terrain walking trial participants were provided a 10 minute rest period before performing the uneven terrain trial. The uneven ground course consisted of a combination of sidewalk and grassy surfaces that best mimic the freeliving conditions individuals ambulate on in Texas. The pedometers were fit to the participants and they moved to the starting line where pedometers were reset to zero. In addition, they were instructed to walk to the cone, then turn around and walk back to the start line, at their normal self-selected pace while an investigator used the hand tally to count actual steps. Upon completion of the walk, participants were instructed to cease motion while pedometer counts were recorded.

Statistical Analysis

Mean and standard deviation of pedometer counts of lower-limb amputees were determined. Repeated-measures (RM) analyses of variance (ANOVAs) were used to examine differences while walking on level and uneven ground using different locations. A single measure intraclass correlation coefficient (ICC) with 95% confidence interval (CI) were computed to assess the agreement between criterion and monitor counts (for each location), with 0.90 or greater considered high agreement; 0.80 to 0.89, moderate agreement; and 0.79 or lower, low agreement.²⁸ Bland-Altman plots of actual counts compared to pedometer counts were used to show any overrepresentation or underrepresentation of steps as well as agreement between measures.²⁹ Scores less than zero indicated an underestimation by the pedometers and scores greater than zero indicated an underestimation by the pedometers. Plots show variability in pedometer scores while still allowing for a mean difference score and 95% limits of agreement to be viewed. If error scores were zero, it indicated no differences between actual steps taken and steps registered by the pedometer. Finally, percentage error was calculated as ([steps detected by pedometer - $AC|/AC$) x 100. The level of significance was set at $p \le 0.05$. All statistical tests were performed using SPSS for Windows version 20 (Chicago, IL, USA).

Results

Participant characteristics can be seen in Table 1. For even ground trials, a repeated measures ANOVA was used to assess the differences in mean step counts among the monitor locations. Results were significant $(F_{(2.1, 21.9)} = 3.58, p = .041)$, with pairwise comparisons indicating the left pocket $(299.7\pm 17.1$ steps) being significantly

greater than the criterion $(288.2 \pm 11.6 \text{ counts})$, $p = .039$. No other comparisons were significantly different, (Table 2). For the uneven ground trials a repeated measures ANOVA was used to assess the differences in step counts among the monitor locations. Since Mauchey's test of Sphericity was significant, $(\chi^2(14) = 38.2, p = .001)$, the Greenhouse-Geisser was used to assess significance of the model. Greenhouse-Geisser was not significant, $(F_{(1.8, 18.6)} = 3.51, p = .05)$, suggesting no significant differences in monitor counts between the criterion for any of the locations (Table 4a, Table 4b). Percentage error during even ground walking were greatest with the pedometer on the neck strap (4.9%), the right pocket (4.7%) and the left pocket (4.7%) with less error on the left hip (2.1%) and right hip (1.2%). Percentage error during uneven ground walking was greatest at the neck strap (6.6%), with error at the left hip (2.9%), left pocket (2.7%), right hip (2.5%) and right pocket (1.9%). For the difference between the means on even ground, the Cohen's d effect size values were as follows: actual count and right pocket $(d=0.89)$, actual count and neck strap $(d=0.78)$, actual count and left pocket $(d=0.78)$, actual count and left hip (*d*= 0.48), actual count and right hip (*d*= 0.30), (Table 2). For the difference between the means on uneven ground, the Cohen's d effect size values were as follows; actual count and neck (*d*=0.90), actual count and left hip (*d*= 0.57), actual count and left pocket (*d*= 0.52), actual count and right hip (*d*= 0.51), actual count and right pocket (*d*= 0.36), (Table 3). The Bland-Altman plots demonstrate mean error amongst the pedometers, and the tighter limit of agreement visible with the right hip pedometer compared with the other pedometer locations on smooth terrain (Figure 1), and tighter limit of agreement seen with the left hip pedometer compared with the other pedometer locations on uneven ground (Figure 2).

	Total $(N = 10)$	Male $(n = 8)$	Female $(n = 2)$
Age, y	47(12.0)	46(13.0)	51(3.0)
Height, cm	163.8(6.7)	164.6(6.8)	160.0(5.0)
Weight, kg	68.2(6.6)	70.1(5.2)	60.0(6.0)
BMI, kg/m^2	23.3(1.7)	25.8(1.5)	23.3(.9)
Classification (n)			
Right transtibial	4	3	
Left transtibial	3	3	0
Right transfemoral			0
Left transfemoral	2		
Reason for prosthesis (n)			
Trauma	3	3	0
Illness		5	\mathcal{D}_{\cdot}

Table 1. Mean (SD) of Participant Characteristics of Lower-Limb Amputees in Texas by Gender.

¹BMI: body mass index
²Illness:; cancers, diabetes type 2, vascular disease

Table 4a. Intramodal Reliability Between Criterion and Activity Monitors on Different Sites During Even Walking Assessed with Chronbach's Alpha and Intraclass Correlation Coefficients (95% confidence interval).

* ICC, intraclass correlation coefficient

Table 4b. Intramodal reliability Between Criterion and Activity Monitors on Different Sites During Uneven Walking Assessed with Chronbach's Alpha and Intraclass Correlation Coefficients (95% confidence interval).

Figure 1. Bland Altman Plots for Pedometer and Actual Counts for Each Location on Even Ground in Texas.

(Criterion + Left Hip)/2 (counts)

Figure 2. Bland Altman Plots for Pedometer and Actual Counts for Each Location on Uneven Ground in Texas.

Discussion

The results of this investigation indicate that during even ground walking the left hip pedometer provided step counts that were significantly greater than actual counts. Although, overall percentage of pedometer error was still under 3% for devices placed on the hip, with highest error seen in the pedometer located at the neck. During uneven ground walking trials there were no significant differences between actual counts and the counts from the various pedometer locations. Also, overall percentage error was highest in the pedometer located at the neck located pedometer**.** An important find in these data is that during uneven ground walking trials, the pedometers appeared to provide lower percent errors, especially when worn at the hip. This finding is similar to that of recent pedometery research taking place in free-living environments. These authors observed more accurate activity measures when walking in outdoor settings.³⁰ When persons walk in free living environments, they might be less hindered by the confines of a structured walking setup. Furthermore, research determining self-selected walking speeds (SSWS) on the treadmill and on free-living surfaces has shown a more reliable method of SSWS determination when walking overground.³¹

This study has some limitations, the first being the small sample size. A larger number of participants, specifically females, can help provide more power. Vascular related amputees made up the majority of the study participants which also limits the ability to make generalizations from this data to all LEA. With the high prevalence of vascular related amputations in the US, it is no surprise that the sample was largely dominated by these types of amputees. 32

Future research could recruit a larger sample which would allow for stratification

of data with respect to amputation etiology and help elucidate accuracy differences in specific amputee groups. The short walking trial of 200m might have been too short a trial to begin to observe authentic gait of each participant. The concept of 'Steady-State' is important when testing the body's physiological responses to walking or exercise. Some authors have suggested allowing the individual to walk for at least four minutes with sampling of the last two minutes for data analysis, 33 however, the verdict for established steady procedures for LEA is still out, 34 and research identifying suitable acclimation and steady state times during walking for LEA should be explored. In addition, walking trials were only performed once during the current study. In order to increase reliability, multiple walking trials should be performed for repeated testing. Based on the results of this study, the Omron HJ-329 pedometer provides acceptable activity counts in indoor and outdoor walking when worn at locations closer to the hip. A prosthetist searching for an objective, accurate and affordable outcome measure can look to this device for repeated clinical use in lower extremity amputees.

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CHAPTER FOUR

DISCUSSION

The research conducted in both developed and resource limited environments provided enough evidence to make important activity monitor recommendations for the lower-extremity amputee population. The first being the ability to confidently recommend the use of the Omron HJ-329 activity monitor for developed and developing environments. The second recommendation of this research stems from the fact that the device was capable of being placed in a number of locations on the body and still provide reliable step counts. A number of authors have tested the accuracy of pedometers in ablebodied populations, $36,40$ with no research recruiting lower extremity amputees in developing nations.⁵⁷ This research centered around designing a study and study setting which could provide a means of testing pedometer accuracy in various placement locations. The testing in both study settings saw most accurate step counts while wearing the pedometer at the hip, a finding that has been observed in previous research as well.⁵⁸ The placement of the pedometer at the hip has consistently been recommended by pedometer manufacturers because it is the vertical acceleration of the hip that appears to be the most reliable indicator of an actual step.⁴⁰ Although the pedometer placed in the pockets and around the neck in the current study were less accurate, on average 4-7% error, they still provided adequate abilities to count steps, however, it is the recommendation of this author for the pedometer to worn at the hip or pocket in order to reduce error to, at or below 3%, the acceptable error percentage for pedometers. $47,59$

Walking on uneven ground has previously been shown to provide more accurate

activity counts.⁴⁸ This might be as a result of individuals feeling less restricted by laboratory or controlled walking pathways. In the current study in the developed setting, step counts also appeared to be more accurate in the uneven walking trial than in the even walking trial. It may well be that amputees walking in developed settings are more comfortable and prepared to walk in the uneven outdoor setting than persons residing in resource limited environments. This might be as a result of better prosthetic technologies, gait training or perhaps increased habitual activity levels. Future research could record habitual physical activity through the use of subjective measurements which could help expand this theory. The developed setting walking trials provided less accurate step counts than in the developing setting study during even walking. There were no significant differences between pedometer and actual counts during uneven walking in the developed setting. There are a few potential causes for this finding, the first being an increase use of endoskeletal componentry and energy storing feet in the developed setting. These technologies have been shown to improve gait and provide a more symmetrical gait, $60,61$ both of which could have helped the participants ambulate with less side to side variations in their CoM and decreased asymmetry in gait, 54 although this cannot be confirmed as the author did not record temporal-spatial or kinetic and kinematic walking data. In addition, the accuracy of pedometers has been shown to increase with increasing walking speed, 40 although walking speed was not calculated in this study. Some of the amputee participants in this study, specifically the transfemoral amputees, exhibited slower walking and minor perturbations during gait as observed by the investigator. This might have caused errors in pedometer counts for this group of amputees.

There are limitations to this study which should be noted. The first being the small number of participants involved in the studies. Furthermore, the cause of amputation for the developing setting research was primarily trauma and the primary cause of amputation in the developed setting was vascular related. There were no children who participated in this study and therefore the results of these investigations cannot be applied to child amputee pedometer recommendations. In this study, the pedometers were not modified to be worn at the wrist of the participants; a growing body of literature is examining the use of wrist worn pedometers. $62,63$

The choice of a 200 meter walkway for walking trials was chosen as it is within the range of feasible distances for the participants to walk, however, the amputee participants might have been unable to reach a 'steady state' walking pattern with a short walk distance. Steady state is an important indicator of a person's physiological acclimation to a set walking condition,⁶⁴ although amputee steady state determinations have been debated.⁴⁴ The addition of one or two more walking trials to repeat testing could also have been performed to increase the reliability of walking trial metrics.

Future Directions

The reliability of the Omron HJ-329 pedometer for use by the lower extremity prosthesis wearer is good and as a result, prosthetists, physical therapists, reimbursement agencies, and amputees can utilize this device as an inexpensive outcome measure and physical activity tracker. Future studies using a larger number of participants need to address limitations of this current research. Also, recruiting equal samples of both vascular and trauma related causes of amputation would allow for stratification of these

groups during data analysis. The current study was unable to recruit a large number of amputees with various amputation causes and was therefore unable to make generalized conclusions for the entire lower extremity amputee population.

Moreover, child amputees were not recruited in the current study and in doing so an important amputee subgroup was not studied. Future research should recruit children because so much research has been designed to investigate child physical activity, 3×10^{-3} measurement of child activity,³⁹ and physical activity for this group has strongly been advocated. Child amputees should also have access to reliable activity monitors and a prosthetist should utilize activity monitors for child prosthesis outcome measurement. As noted, the underlining biomechanical causes for decreased pedometer accuracies which were observed at the neck and pocket locations were not explored. Future studies could combine temporal-spatial, kinematic and kinetic measures with step activity measurements to help identify possible causes of device error. The uneven surface pathways in the current study might not be capable of being replicated in other studies. Creation of an uneven pathway or a systematic uneven pathway protocol can provide a method for repeating uneven terrain pathway testing in a variety of settings around the globe.

Conclusion

Physical activity and its measurement is important in order to promote a better quality of life for persons with lower-extremity amputations. The basis for measurement of physical activity is the need to measure and evaluate a persons activity levels with reference to norms or as an objective outcome measurement for activity or various rehabilitation interventions. The measurement of activity by using the Omron HJ-329

pedometer is a suitable method for facilitating outcome measurement and self-physical activity assessment in LEA. Although the intended use of this device was for able-bodied persons, the use of the device can be expanded to both trauma and dysvascular amputees living in developed and RLEs ambulating on a variety of terrains. The ease of use of the monitor makes it an easy adoption to a toolbox of practitioner outcome measures. The practitioner need only understand the standard operating procedures of the monitor and explain them to the patient. The data retrieved from the pedometer is beneficial to the practitioner because it can provide a snapshot of patient activity before and after a prosthesis intervention. This data is relevant and useful because the practitioner can identify if and to what extent the intervention is promoting physical activity. Mobility and improved quality of life will remain vital outcomes for the prosthetist and will therefore necessitate measurement and evaluation of acute and chronic physical activity of all amputee patients.

Furthermore, the low cost of the device, approximately \$27 USD, makes it affordable for small and large O&P clinics in developed and resource limited environments. Although, the metrics derived from pedometers are limited to daily and weekly step counts, they are still valuable and more importantly, discernable by medical professionals and patients alike. There is no need to download data into complex and often costly software. The user only needs to record step count values from an easily readable pedometer screen. It is hoped that activity monitor manufacturers consider the importance of activity monitoring for the small but often marginalized subpopulation of amputees. In doing so, activity monitoring as an outcome measure, can easily become a standard of care for prosthetic and orthotic treatment throughout the world.

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