

Effectiveness of Prosthetic Feet, Lower Function - Request for Proposals 2015
 American Orthotics and Prosthetics Association (AOPA)

The American Orthotic & Prosthetic Association is interested in promoting research focused on improving the knowledge about prosthetic feet, specifically a comparison of performance and patient outcomes of lower function prosthetic feet that are available without pre-payment audit or delay vs. those codes/prosthetic feet that typically have been identified by Medicare contractors for greater scrutiny and often promises of universal prepayment audit.

TITLE OF PROJECT: Comparative Effectiveness of Prosthetic Feet, Lower Function

INVESTIGATORS:

Name(s): (list Principal investigator on line 1)				
1. Kenton R. Kaufman				
2.				
3.				
4.				

FUNDS REQUESTED: _\$175,000_

NAME OF RESPONSIBLE INVESTIGATOR: _____
 (to be completed if Principal Investigator is a trainee)

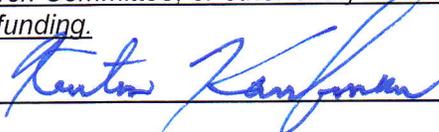
IRB STATUS:

Approved	Pending	Approval Not Required
	XXX	

CONFLICT OF INTEREST:

None	Potential	Yes
XXX		

As the principal (or responsible investigator, if applicable), I agree that if this grant proposal is funded, I will acknowledge the AOPA's support in all publications that arise from the research. I also will submit to the AOPA Research Committee, or other entity so designated, a final report 18 months after the receipt of funding.

Signature of Principal Investigator: 

Signature of Responsible Investigator (required if Principal Investigator is a trainee): _____

Institution: Mayo Clinic

Address: 200 First Street SW

Address: Charlton North, Lobby 110L

City: Rochester State: MN Zip: 55901 Country: USA

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E-mail: kaufman.kenton@mayo.edu

ABSTRACT

Lower limb amputees require increased functionality in prosthesis design. However, the current audit intensive environment has challenged prosthetic care providers to justify advanced technology prosthetic feet. Presently there are two distinct types of foot components for transtibial amputees: microprocessor controlled feet (MPF) and non-microprocessor controlled prosthetic feet (NMPF). Both of these general classes of prosthetic knees are currently used in the marketplace (L5981 and L5973). The MPF have a smooth rollover, increased range of motion, and improved swing phase clearance. These design features should translate into improved functional efficacy, improved patient satisfaction, and reduced falls. However, there is a paucity of studies to document outcomes. Therefore, *the purpose of this study is to evaluate the comparative effectiveness of subjects using two types of prosthesis designs: MPF vs NMPF.*

Thirty experienced transtibial amputees will be studied in their free-living community environment. Their physical activity will be assessed using a unique activity monitor device developed at Mayo Clinic. Their socket comfort and quality of life will be assessed with questionnaires. Their fall experience will also be quantified using a questionnaire. We hypothesize that the amputees using the MPF will have increased activity with reduced compensatory movements. These performance features will result in increased patient satisfaction along with a reduced fall rate.

SPECIFIC AIMS

According to the Congressional Budget Office, approximately \$700 billion is spent every year on health care that has not been shown to lead to better health outcomes [1]. Americans spend more per capita on health care than any other nation, currently about 16 percent of the GDP [2], but still rank far behind other industrialized nations in terms of health care outcomes [3]. Because of the rising cost of health care without corresponding returns in health outcomes, comparative effectiveness research has gotten increased attention. Current clinical practice is often to adopt newer, more expensive treatments without a full understanding of any added benefit over prior state-of-the-art options. Pressure is mounting to become accountable for the quality of care provided in clinical practice. In prosthetics, evidence exists to inform clinical practice, but additional research is needed to confirm existing evidence and better understand outcomes associated with the prescription of prosthetic feet. ***Thus, this proposal will assess if the functional performance and musculoskeletal outcome of transtibial amputees are improved after receiving a microprocessor-controlled foot (MPF) compared to a non-microprocessor-controlled foot (NMPF).*** A multi-disciplinary team with expertise in biomechanics, rehabilitation, and prosthetics has been assembled to investigate two Specific Aims:

Specific Aim 1: Quantify the functional efficacy of transtibial amputees wearing different prosthetic feet.

Hypothesis 1a: Subjects will increase their activity levels when using a MPF; and

Hypothesis 1b: Subject will have improved gait symmetry when using a MPF.

Changes in activity level will be evaluated in the free-living environment using a novel activity monitor. A NMPF provides a restrictive effect on the sound side stride length whereas a MPF allows controlled dorsiflexion which facilitates a reduction in restriction in sound side stride length. MPF have a smooth roll over and increased range of motion which facilitates improved gait symmetry and increased activity levels.

Specific Aim 2: Quantify the satisfaction of transtibial amputees wearing different prosthetic feet.

Hypothesis 2a: There will be a reduction in anterior distal socket pain/discomfort with a MPF; and

Hypothesis 2b: Subject perception of Quality of Life (QOL) will be improved with a MPF.

Socket comfort will be evaluated with the prosthetic socket fit comfort score. Quality of life will be graded using the Short Form (36) Health Survey Questionnaire (SF-36) and the Prosthesis Evaluation Questionnaire (PEQ). The hypothesized changes in socket comfort will be due to differences in the clockwise moment occurring at initial contact. The anterior contact is only partially cushioned by the shock absorbance capability of heel of a carbon fiber foot, whereas introduction of a MPF further reduces the clockwise moment with a resultant increase in comfort and quality of life.

Specific Aim 3: Assess the safety of transtibial amputees wearing NMPF vs MPF.

Hypothesis 3: Differences exist in stumble and fall rates between amputees using MPFs and NMPFs.

Stumble and fall rates will be assessed with the PEQ addendum questionnaire (PEQ-A) and telephone calls. A MPF will facilitate increased dorsiflexion during the swing phase of gait. It is anticipated that the improved swing phase clearance will be associated with a reduction in stumbles and falls.

Findings from this research study will have immediate applicability. Specifically, these results will help determine which patients will benefit from advances in computerized prosthesis technology. Accordingly, health care professionals and payers will have clearer guidelines for use of computerized prosthetic knees.

BACKGROUND/SIGNIFICANCE

There are a number of presently available cost-effective foot components for transtibial amputees [4, 5]. Dynamic elastic response (DER) feet are prostheses that store and release energy during gait. They are designed for active amputees [6] and believed to be or greater beneficial to lower-limb amputees as compared to the wooden SACH foot because they facilitate improved mobility and functionality of people with lower-limb amputation [7]. Several studies have tried to quantify differences in patient's function with commercially available prosthetic feet that could be used to guide prescriptions [8-11]. Yet, at present, there is little scientific evidence to guide the clinical prescription of prosthetic feet [12]. One

double-blind randomized controlled trial has been conducted and demonstrated that differences in foot designs do reflected in difference in patient function [13]. Yet, prosthetic guidelines are currently based on clinical consensus among experts[14]. No clinical guidelines exist to provide guidance for prosthetic prescriptions. Third-party payers require justification for provision of costly prostheses [15]. Consumers are seeking objective information to aid in decision making with regards to prosthetic options they are offered in attempts to improve their quality of life. Therefore, comprehensive studies are needed to form a solid basis for prosthetic prescription. ***The proposed study seeks to gather additional experience of community-living, transtibial amputees using MPFs. We hypothesize that MPFs will result in improved activity in the free-living environment, increased patient satisfaction, decreased discomfort and a reduced fall rate.***

Our previous and current research activities demonstrate our abilities to conduct this proposed research program and yield novel research findings. Over the past decade, we have been actively conducting comparative effectiveness studies in both orthotics and prosthetics. Of particular relevance to this proposal is our objective comparison of MPKs to NMPKs [16-19] More recently, we have demonstrated the able to quantify activity in the free-living environment using novel algorithms developed at Mayo Clinic [20, 21]. We currently use a tri-axial accelerometer (Fig 1) to measure 3D acceleration, record the data using on-board memory, and then have the subject send the monitor back to us for the data to be downloaded and analyzed. The activity monitor has been used to record the activities-of-daily-living of K2 transfemoral amputees for four continuous days while using a NMPK. These data reveal differences in activity levels (Fig 2), differences in amount of load-bearing activity (Fig 3) and differences in cadence (Fig 4). It is important to notice that the activity, load-bearing activity and cadence are not closely associated. These data *demonstrate our ability to measure activity level in the field over multiple continuous days and provide a meaningful interpretation. These data are able to provide a unique perspective on the patient’s prosthetic usage.*



Figure 1. ActiGraph GT3X+ activity monitor. The monitor is the size of a wrist watch. It is configured to continuously collect data for greater than a week and store the data in on-board memory. The ambulatory monitor uses a 3-axis accelerometer to measure human movement. The monitor measures 4.6cm x 3.3cm x 1.9cm and weighs 19 g. The monitor can be programmed for data collection rates up to 100 Hz.

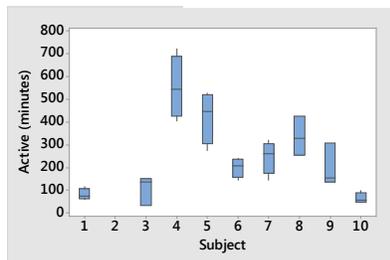


Figure 2. Daily activity levels of 10 transfemoral amputees using a NMPF. The activity levels ranged from 65 to 555 minutes/day.

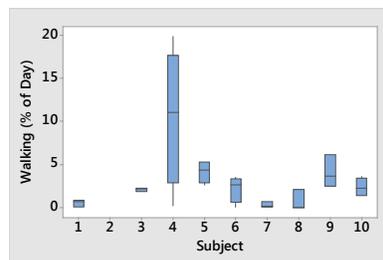


Figure 3. Load-bearing activity during the day for 10 transfemoral amputees using a NMPK. The proportion of the day spent in load-bearing ranged from 0.3 to 10.5% of the day.

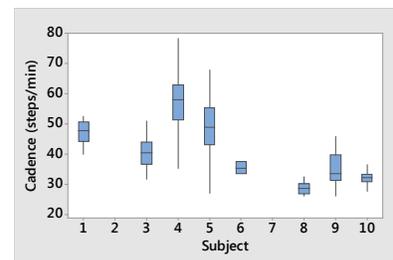


Figure 4. Variable cadence during daily living of K2 transfemoral amputees using a NMPK.

RESEARCH PLAN

Study Design: The study design is a reversal design whereby only the prosthetic foot will be changed. Each subject will be tested using their current NMPF, fit and tested with a MPF, and then tested again with a NMPF, e.g. A-B-A design. This design was chosen over the A-B-A-B design, because the A-B-A-B design offers no analytical advantage. Prosthetic feet from all manufacturers will be considered

appropriate for testing. Each subject will be given an acclimation period (typically ~4 months) consistent with other similar studies [22, 23] before testing is commenced on the MPF, since one week has been shown to be too short of an acclimation time [24]. The NMPF foot will be in the following classes that are all considered K3 feet: L5976 class, e.g. Energy storing foot (Seattle Carbon Copy II or equal); L5979 class, e.g. Dynamic response foot with multi-axial ankle; L5980 class, e.g. Flex foot system; L5981 class, e.g. Flex-walk system or equal. The MPF foot will be in the L5973 class. The same socket and suspension will be used throughout the study in order to eliminate these confounding variables.

Research Participants: 30 unilateral transtibial amputees over the age of 21 who are Medicare Functional Classification Level K3 will be studied using this protocol. Subjects will be recruited who have at least 2 years' experience using a prosthesis. Stump volume must not have fluctuated significantly within the past six months to be considered for this study. Subjects must have no other neuromuscular problems such as a previous stroke or a partial amputation of the contralateral limb that would preclude them from performing the test protocol. Subjects will be excluded if they are on dialysis or require gait aids for ambulation. They will also be excluded if they have poor prosthetic socket fit or have stump problems, e.g. skin breakdown. No restrictions will be placed on gender or race. The protocol for this study will be approved by the local Institutional Review Board. The experimental procedures will be explained to the subject and written consent will be obtained prior to enrollment into the study.

Patient Function (Efficacy): Field based measurements will be obtained using activity monitors attached to waist, and bilaterally to the ankle and thigh for a period of 4 consecutive days. The subject will don the monitors in the morning after waking and remove them prior to sleeping. See above for more details.

Patient Satisfaction: The subject's self-assessed satisfaction during the previous four weeks in their free-living environment will be measured at the end of each prosthetic rotation. Prosthetic socket comfort will be assessed using the Socket Comfort Score (SCS). The SCS has demonstrated repeatability, criterion related validity, and sensitivity to change [25]. The general health SF-36v2 questionnaire and condition-specific Prosthesis Evaluation Questionnaire (PEQ) will be used to quantify patient satisfaction [26].

Patient Safety: The subject's safety during the previous four weeks in their free-living environment will be measured at the end of each prosthetic rotation. The PEQ addendum (PEQ-A) will also be administered to the subjects. The PEQ-A is 14 additional questions used to quantify subject confidence, concentration, stumbles, and falls [27]. The recall period is 4 weeks, since recall periods longer than 5 weeks may underestimate the true episodes [28]. Bi-weekly phone calls will be made to maintain patient contact.

Data Analysis: The purpose of this study is to compare the functional efficacy, patient satisfaction, and safety of two prosthesis designs: MPF vs. NMPF. The effects of these two prosthesis designs on these outcome variables will be evaluated using a one-factor repeated measures ANOVA. If the data are not sufficiently Gaussian, a non-parametric procedure such as Friedman's test will be used. Comparisons of A1 versus B, and A2 versus B will be also conducted using multiple comparison procedures or contrasts following the global ANOVA or Friedman's test. All procedures and analysis methods proposed in this study have been used previously and have been thoroughly validated.

Efficacy: The tri-axial accelerometer signals will be processed to yield activity levels of none, low, medium and high. Statistical analysis will determine if there are differences in activity level between the two prosthetic designs. Post-hoc analyses will be performed to determine which activity subscales differ between the prosthetic designs. Asymmetry between the prosthetic and non-prosthetic limb will be quantified using the asymmetry index described by Kaufman et al [29]. Age related changes in gait will also be quantified.

Patient Satisfaction: The SCS will provide a measure of numerical rating of comfort, where 0 and 10 represent the most uncomfortable and the most comfortable socket imaginable. The SCS results will be assessed with non-parametric analyses. The SF-36 will be used to determine if quality of life improves with a MPF. A multivariate approach will be used to compare all PEQ subscales simultaneously. If the overall test is significant, post-hoc analyses will be performed to determine which subscales differ between prosthetic designs.

Patient Safety: The PEQ-A will be grouped according to subject matter content (concentration, confidence, stumbles, falls) and tested to determine if there are differences due to prosthetic design.

Sample size: We will use a pilot test to finalize the sample size. The study power is based on an effect-size approach [30]. Based on a paired design with 30 subjects enrolled, there will be 80% power to detect differences in means between the two devices (MPF vs. NMPF) of at least 0.51 standard deviations, which is considered to be a medium effect size. This sample size is larger than previous microprocessor-controlled knee studies [17, 27, 31], where the number of subjects ranged from 15 to 21.

POTENTIAL LIMITATIONS AND SOLUTIONS

Recruitment: We will work with prosthetic practices throughout the US to recruit subjects. We have already identified a large cohort of patients who could potentially participate in this study.

Fall Reporting: The safety data is directly linked to the ability to accurately monitor falls [32]. All methods, except recall, have the drawback of increasing burden on the research participants. The use of recall is limited by the extent of memory decay over time, true under- or over-estimation, and intervention bias [33-35]. Yet, recall may be the most accurate because the subject is often a witness to the event with proximity, saliency, and attachment to the event. Kahle [31] has justified the use of subject recall in a similar study on transtibial amputee fall rates.

TIMELINE

This study will be completed in one year, as specified in the RFP.

RESPONSIVENESS TO REQUEST

The RFP seeks proposals for a comparative effectiveness study between the performance and patient outcomes, in the laboratory and/or in community mobility and activities of daily living between lower function prosthetic feet that are available without pre-payment audit or delay vs. those codes/prosthetic feet that typically have been identified by Medicare contractors for greater scrutiny and often promises of universal prepayment audit.

In response, we will collect the primary outcome endpoints efficacy, patient satisfaction and patient safety. All data will be collected in the field-environment. The feet being tested represent L5981 class, e.g. flex foot or equivalent, and L5973 class, which has received increased scrutiny by Medicare contractors.

REFERENCES

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3. Central Intelligence Agency, Online Publications, The World Factbook. Country Comparisons-People. <https://www.cia.gov/library/publications/the-world-factbook/rankorder/rankorderguide.html>.
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General Information	
Principal Investigator	Kenton R Kaufman
Funding Proposal Title	Comparative Effectiveness of Prosthetic Feet, Lower Function
Funding Source	American Orthotic and Prosthetic Association
External ID	
Funding Proposal ID	FP00083133
Budget ID	BU00128388
Budget Title	Comparative Effectiveness of Prosthetic Feet, Lower Function

PERSONNEL		
		Period 1
		4/30/2015
		4/29/2016
NAME	Role	
Kaufman, Kenton R	PD/PI	
Salary Effort Requested		0.000%
Calendar Months		0.00
Bernhardt, Kathie Ann	Study Coordinator	
Salary Effort Requested		75.000%
Calendar Months		9.00
Fortune, Emma, PhD	Post Doctoral	
Salary Effort Requested		95.000%
Calendar Months		11.40
Total PERSONNEL (salary & fringe benefit)		\$137,050

PATIENT CARE		
		Period 1
		4/30/2015
		4/29/2016
Patient Care Schedule (PCS)	Total	
PCS00006140 - Comparative Performance of Dynamic Elastic Response Feet		\$7,937
# of Patients		30
Total Patient Care		\$7,937

SUPPLIES AND EXTERNAL SERVICES		
		Period 1
		4/30/2015
		4/29/2016
Accounting Category	Description	
Medical/Surgical/Lab Supplies	Activity Monitors:, \$300/monitor * 4, monitors/set * 5, sets	\$6,000
Other Fees and Services	Postage:, \$12/ mailing * 2, mailings/collection *, 150 collections	\$1,800
Office and General Supplies	Office and General Supplies	\$2,025
Total Supplies		\$9,825

INTERNAL SERVICES		
		Period 1
		4/30/2015
		4/29/2016
Accounting Category	Description	
Med Statistics. Data Analyst	Med Statistics. Data Analyst	\$5,000
Total Internal Services		\$5,000

Subtotal Direct Cost	\$159,812
Total Direct Cost	\$159,812
MTDC	\$151,875
Indirect Rate	10.000%
Total Indirect Cost	\$15,188
Total Cost	\$175,000

ADMINISTRATIVE PERSONNEL	
Accountant	Jack Wilson
Administrator	Phillip Lombardo
Contract Manager	Lourde Soop
Specialist, PreAward	Tony Haglund
Specialist, PostAward	Michelle Kvall
Last Modified	3/27/2015 12:26:43 PM

FOOTNOTES

Foundation does not allow PI effort and Mayo Clinic requires a minimum of 1% effort for the Pi so that 1% will need to be supplemented. Also the foundation only allows 10% indirect rate so the remaining 20% will also need to be supplemented.

E. IRB Approval Letter

IRB approval is pending.

F. Conflict of Interest Statement

The investigators have no conflicts of interest to declare. They do not receive any money related to the design, production, or use of prosthetic feet.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Kenton R. Kaufman	POSITION TITLE-Professor, Biomedical Engineering Director, Motion Analysis Laboratory		
eRA COMMONS USER NAME KAUFMAN1	W. Hall Wendel, Jr. Musculoskeletal Research Professor		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
South Dakota State University, Brookings, SD	B.S.	1974	Ag. Engineering
South Dakota State University, Brookings, SD	M.S.	1976	Ag. Engineering
North Dakota State University, Fargo, ND	Ph.D.	1988	Biomech. Engineering
Mayo Graduate School of Med., Rochester, MN	Postdoc	1989	Biomech. Engineering

Please refer to the application instructions in order to complete sections A, B, and C of the Biographical Sketch.

A. POSITIONS AND HONORS

1976-1985: Assistant Professor, Agricultural Engineering Dept, North Dakota State University, Fargo
 1983: Consultant, United Nations Industrial Development Organization, Vienna, Austria
 1985-1986: Graduate Teaching Fellow, Ag. Engineering Dept, North Dakota State University, Fargo
 1986-1988: Visiting Scientist, Orthopedic Biomechanics Laboratory, Mayo Clinic, Rochester, MN
 1988-1989: Research Fellow, Orthopedic Biomechanics Laboratory, Mayo Clinic, Rochester, MN
 1989-1996: Director, Orthopaedic Research, Children's Hospital and Health Center, San Diego
 1992-1994: Assistant Professor, University of California, San Diego, California
 1994-1996: Associate Professor, University of California, San Diego, California
 1996-2004: Associate Professor of Bioengineering, Mayo Clinic/Mayo Foundation, Rochester, MN
 1996-2004: Consultant, Dept of Orthopedic Surgery, Mayo Clinic/Mayo Foundation, Rochester, MN
 1996-Present Director, Biomechanics Laboratory, Mayo Clinic/Mayo Foundation, Rochester, MN
 2004-Present Consultant, Orthopedic Surgery, Physiology and Biomedical Engineering, Mayo Clinic
 2004-Present Professor of Biomedical Engineering
 2007-Present W. Hall Wendel, Jr. Musculoskeletal Research Professor

PROFESSIONAL LICENSURE: Registered Professional Engineer

HONORS

Honorary fraternities: Alpha Epsilon, Tau Beta Pi, Sigma Tau, Phi Kappa Phi, and Gamma Sigma Delta
 Sigma Xi, Scientific Research Society of North America
 1989: Excellence in Research Award, American Orthopedic Society for Sports Medicine
 1989: Young Scientist Award, American Society of Biomechanics
 1993: O'Donoghue Sports Injury Research Award, American Orthopedic Society for Sports Medicine
 1993 – 2005: NIH Study Section Reviewer
 1996: Clinical Research Award, Orthopedic Research and Education Foundation, AAOS
 1998: Reviewer, National Institute on Disability and Rehabilitation Research
 1998 & 2002: Best Scientific Paper, Gait and Clinical Movement Analysis Society
 2001 - 2002: President, Gait and Clinical Movement Analysis Society
 2002: Fellow, American Institute of Medical and Biological Engineers
 2004 - 2005: Reviewer, Centers for Disease Control
 2005-2009: Member, Musculoskeletal Rehabilitation Sciences Study Section, NIH
 2006 - 2007: President, American Society of Biomechanics

2007: Distinguished Alumni, South Dakota State University
 2008: Distinguished Engineer, South Dakota State University
 2008: Frank Stinchfield Award, Hip Society
 2011: Fellow, American Society of Biomechanics
 2011-Present: Member, National Advisory Council for Nursing Research, NIH
 2012: John Insall Award, Knee Society
 2012: Best Poster Award, European Society of Movement Analysis for Adults and Children
 2013 Borelli Award, American Society of Biomechanics
 2014 Research Award, American Academy of Orthotists and Prosthetists
 2015 Fellow, American Society of Mechanical Engineers

B. SELECTED PUBLICATIONS: (Selected from over 200 scientific peer-reviewed publications)

Most relevant to the current application

1. Kaufman KR, Miller L, and Sutherland DH. Gait asymmetry in patients with limb-length inequality. *Journal of Pediatric Orthopaedics*, 16(2):144-150, 1996.
2. Kaufman KR, Irby SE, Mathewson JW, Wirta RW, and Sutherland DH. Energy efficient knee ankle foot orthosis. *Journal of Prosthetics & Orthotics* 8(3):79-85, 1996.
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H. Supporting Letters

Dale Berry-Hanger Orthopedic Group, Inc.

K. Michael Fillauer-Fillauer

Sigurdur G. Gissurarson-Ossur

Andreas Kannenberg-OttoBock

Christopher J. Nolan-Endolite



March 25, 2015

Kenton R. Kaufman, Ph.D., P.E.
W. Hall Wendel Jr Musculoskeletal Research Professor
Professor of Biomedical Engineering
Director, Biomechanics/Motion Analysis Laboratory
Consultant, Departments of Orthopedic Surgery, Physiology and Biomedical Engineering
Mayo Clinic
Charlton North L-110L
200 First Street SW
Rochester, MN 55905

RE: AOPA Grant Proposal on Comparative Effectiveness of Prosthetic Feet, Lower Function

Dear Dr. Kaufman,

I'm writing this letter to provide my strongest support for your proposed research project to study the comparative effectiveness of prosthetic feet. I fully support this project as it will I feel that the O&P profession will benefit from a more structured and evidence-based outcome study.

As you know, the literature and evidence to date are primarily anecdotal and insufficient to support many of the claims made. Based on experience, patient reports, expert opinions and design features, it appears that they may be an advantage of microprocessor-controlled feet. However, there is currently no peer-reviewed literature to provide conclusive evidence-based recommendations for the use of one prosthetic foot over another. Therefore, the study you are proposing is especially timely and relevant.

I understand that the role of Hanger Clinic will be to provide research support for the proposed project. We will provide support in two ways. First, we will assist with identifying patients who qualify to be enrolled into the study. Second, our clinical team will provide the prosthetic fitting of the feet used in the study.

I look forward to this collaborative study. I strongly believe that combining your research expertise with our clinical capabilities will create the highest level of excellence for this comparative effectiveness study. I am also pleased because this project will allow us to develop a strong collaboration for future research projects.

Sincerely,

Dale Berry, CP, FAAOP, LP
Vice President, Clinical Operations
Hanger Clinic



March 25, 2015

Kenton R. Kaufman, Ph.D., P.E.
W. Hall Wendel Jr Musculoskeletal Research Professor
Professor of Biomedical Engineering
Director, Biomechanics/Motion Analysis Laboratory
Consultant, Departments of Orthopedic Surgery, Physiology and Biomedical Engineering
Mayo Clinic
Charlton North L-110L
200 First Street SW
Rochester, MN 55905

RE: AOPA Grant Proposal on Comparative Effectiveness of Prosthetic Feet, Lower Function

Dear Dr. Kaufman,

We are writing this letter to provide our support for your proposed research project to study the comparative effectiveness of prosthetic feet. We are especially excited to participate in this project because the O&P profession will benefit from a more structured and evidence-based outcome study.

Founded in 1914 in Chattanooga, TN, Fillauer is a manufacturing and clinical leader in the orthotic and prosthetic industry. Our product, Raize, is one of the premier microprocessor-controlled prosthetic feet on the market. This foot is revolutionary because it provides active control of ankle range of motion and terrain compliance.

We understand that the role of Fillauer will be to provide support for the proposed project in two ways. First, we will provide three microprocessor-controlled feet and associated componentry to be used for subjects enrolled into the study. Second, our technical support staff will be present at the prosthetic fitting to assure that the components are installed correctly. Third, we will refurbish the feet between subjects so that the warranty is valid for all subjects tested.

We look forward to collaborating with you on this comparative effectiveness study. We recognize the combined clinical and research expertise being assembled for this study. The capabilities of this team will create the highest level of excellence for this comparative effectiveness study. We are very pleased to participate in this project.

Sincerely,

K. Michael Fillauer, CPO
President
Fillauer LLC

March 25, 2015

Kenton R. Kaufman, Ph.D., P.E.
W. Hall Wendel Jr Musculoskeletal Research Professor
Professor of Biomedical Engineering
Director, Biomechanics/Motion Analysis Laboratory
Consultant, Departments of Orthopedic Surgery, Physiology and Biomedical Engineering
Mayo Clinic
Charlton North L-110L
200 First Street SW
Rochester, MN 55905

RE: AOPA Grant Proposal on Comparative Effectiveness of Prosthetic Feet, Lower Function

Dear Dr. Kaufman,

We are writing this letter to provide our support for your proposed research project to study the comparative effectiveness of prosthetic feet. We are especially excited to participate in this project because the O&P profession will benefit from a more structured and evidence-based outcome study.

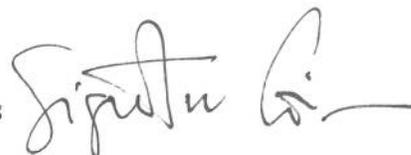
ÖSSUR is a leader in the prosthetic market. Our company was founded in 1971 and has wide-ranging expertise in the development, production, and sale of non-invasive orthopaedics. After its first listing on the Iceland Stock Exchange in 1999, the Company expanded rapidly through a series of strategic acquisitions. Significant ongoing investment in research and innovation has also been central to its growth. A global leader in the field, Össur is determined to further strengthen its market position. The Company has been listed on the NASDAQ OMX Copenhagen Stock Exchange since 2009.

Headquartered in Iceland and employing a staff of around 2,200 across 18 locations, Össur has extensive operations in the Americas, Europe, and Asia, with numerous distributors in other markets. Our product, the Proprio Foot, is one of the leading microprocessor-controlled prosthetic feet on the market. This foot is revolutionary because PROPRIO FOOT is an adaptive prosthetic device that mimics natural foot motion. Motor-powered ankle motion increases ground clearance and reduces the risk of tripping and falling. This allows users to traverse different kinds of terrain in a natural and secure way.

We understand that the role of ÖSSUR will be to provide support for the proposed project in two ways. First, we will provide three microprocessor-controlled feet and associated componentry to be used for subjects enrolled into the study. Second, our technical support staff will be present at the prosthetic fitting to assure that the components are installed correctly. Third, we will refurbish the feet between subjects so that the warranty is valid for all subjects tested.

We look forward to collaborating with you on this comparative effectiveness study. We recognize the combined clinical and research expertise being assembled for this study. The capabilities of this team will create the highest level of excellence for this comparative effectiveness study. We are very pleased to participate in this project.

Sincerely,
Sigurdur G. Gissurason
Dir. Product Marketing Management Prosthetics Americas



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Rochester, MN 55905

March 30, 2015

RE: AOPA Grant Proposal on Comparative Effectiveness of Prosthetic
Feet, Lower Function

Dear Dr. Kaufman,

We are writing this letter to provide our support for your proposed research project to study the comparative effectiveness of prosthetic feet. We are especially excited to participate in this project because the O&P profession will benefit from a more structured and evidence-based outcome study.

Otto Bock HealthCare was founded in 1919 and is a global leader in the prosthetic industry. Our product, Triton Smart Ankle, is one of the leading microprocessor-controlled prosthetic feet on the market.

We understand that the role of Ottobock will be to provide support for the proposed project in two ways. First, we will provide three microprocessor-controlled feet and associated componentry to be used for subjects enrolled into the study. Second, our technical support staff will be present at the prosthetic fitting to assure that the components are installed correctly. Third, we will refurbish the feet between subjects so that the warranty is valid for all subjects tested.

We look forward to collaborating with you on this comparative effectiveness study. We recognize the combined clinical and research expertise being assembled for this study. The capabilities of this team will create the highest level of excellence for this comparative effectiveness study. We are very pleased to participate in this project.

Sincerely,

A handwritten signature in blue ink, appearing to read "A. Kannenberg", with a stylized flourish extending to the right.

Andreas Kannenberg, M.D., Ph.D.
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March 25, 2015

Kenton R. Kaufman, Ph.D., P.E.
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Director, Biomechanics/Motion Analysis Laboratory
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Mayo Clinic
Charlton North L-110L
200 First Street SW
Rochester, MN 55905

RE: AOPA Grant Proposal on Comparative Effectiveness of Prosthetic Feet, Lower Function

Dear Dr. Kaufman,

We are writing this letter to provide our support for your proposed research project to study the comparative effectiveness of prosthetic feet. We are especially excited to participate in this project because the O&P profession will benefit from a more structured and evidence-based outcome study.

Blatchford/Endolite is a leader in the prosthetic market. Our company was founded in 1890 and is one of the leading providers of innovative prosthetic devices in the industry. Our product, **the Elan**, is one of the leading microprocessor-controlled prosthetic feet on the market. *This foot is revolutionary because it is a hydraulically controlled ankle that provides instantaneous and continuous control of the prosthetic foot while in stance phase providing for unparalleled compliance with terrain during ambulation. In addition to providing ground clearance during swing phase, the **Elan** offers a brake and assist mode during ambulation to allow for easier transitions between level ground, slopes and fast walking*

We understand that the role of Blatchford/Endolite will be to provide support for the proposed project in two ways. First, we will provide three microprocessor-controlled feet and associated componentry to be used for subjects enrolled into the study. Second, our technical support staff will be present at the prosthetic fitting to assure that the components are installed correctly. Third, we will refurbish the feet between subjects so that the warranty is valid for all subjects tested.

We look forward to collaborating with you on this comparative effectiveness study. We recognize the combined clinical and research expertise being assembled for this study. The capabilities of this team will create the highest level of excellence for this comparative effectiveness study. We are very pleased to participate in this project.

Sincerely,

Christopher J. Nolan

Christopher J. Nolan
Vice President & General Manager
Endolite

I. Appendices

The key technology used in this study is our ability to monitor activity in the free-living environment. The three attached articles demonstrated the capabilities of our measurement techniques.

Lugade V, Fortune E, Morrow M, Kaufman K. Validity of using tri-axial accelerometers to measure human movement – Part I: Posture and movement detection. *Medical Engineering & Physics*, 36:169-176, 2014 Feb. PMC3866210. PMID23899533

Fortune E, Lugade V, Morrow M, Kaufman K. Validity of using tri-axial accelerometers to measure human movement – Part II: Step counts at a wide range of gait velocities. *Medical Engineering & Physics*, In press, 2014. PMC4030415. PMID24656871.

Fortune E, Lugade V, Kaufman K. Posture and Movement Classification: The comparison of tri-axial accelerometer numbers and anatomical placement. *Journal of Biomechanical Engineering*, 136(5): 051003, April 2014. PMC4023813. PMID24337255.

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Validity of using tri-axial accelerometers to measure human movement—Part I: Posture and movement detection



Vipul Lugade, Emma Fortune, Melissa Morrow, Kenton Kaufman*

Motion Analysis Laboratory, Division of Orthopedic Research, Mayo Clinic, Rochester, MN 55905, USA

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ABSTRACT

A robust method for identifying movement in the free-living environment is needed to objectively measure physical activity. The purpose of this study was to validate the identification of postural orientation and movement from acceleration data against visual inspection from video recordings. Using tri-axial accelerometers placed on the waist and thigh, static orientations of standing, sitting, and lying down, as well as dynamic movements of walking, jogging and transitions between postures were identified. Additionally, subjects walked and jogged at self-selected slow, comfortable, and fast speeds. Identification of tasks was performed using a combination of the signal magnitude area, continuous wavelet transforms and accelerometer orientations. Twelve healthy adults were studied in the laboratory, with two investigators identifying tasks during each second of video observation. The intraclass correlation coefficients for inter-rater reliability were greater than 0.95 for all activities except for transitions. Results demonstrated high validity, with sensitivity and positive predictive values of greater than 85% for sitting and lying, with walking and jogging identified at greater than 90%. The greatest disagreement in identification accuracy between the algorithm and video occurred when subjects were asked to fidget while standing or sitting. During variable speed tasks, gait was correctly identified for speeds between 0.1 m/s and 4.8 m/s. This study included a range of walking speeds and natural movements such as fidgeting during static postures, demonstrating that accelerometer data can be used to identify orientation and movement among the general population.

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1. Introduction

Identifying human body position and movement in the free-living environment can provide subject-specific data on activity or disability as well as elucidate changes due to intervention or rehabilitation among patients [1]. Accelerometer based activity monitors provide objective measurements of patient function during free-living [2,3], and have been used in a variety of populations including healthy individuals, patients with Parkinson's disease [4], total hip arthroplasty [5], and osteoarthritis [6]. Central to the clinical and research utility of activity monitors is the validity of analysis methodologies, applied to the raw body accelerations, to decipher static body postures and dynamic movement activities during activities of daily living (ADLs). Further, for clinical efficacy,

the validation procedures must go beyond controlled conditions that test human movement which is considered “normal” and typical of healthy individuals. Slow walking is often characteristic of disease and disability, and patients with a decreased walking speed are at high risk for functional decline, morbidity, and mortality [7,8]. In addition to the inclusion of a wide range dynamic activity in validation procedures, it is important to include walking performed at slow speeds for applicability of the analysis methodology to patient populations.

Commercial devices such as the Intelligent Device for Energy Expenditure and Activity (IDEEA) [9], DynaPort MoveMonitor [10], and the activPAL [11] have demonstrated the ability to discriminate posture, though the description of methodologies are absent or lacking, with detection algorithms based on third party black box classification. Previous validation studies report highly accurate results, though movements were performed in a controlled environment measuring only a limited set of postures, neglecting transitions between postures [9,12], and collecting over a narrow range of walking speeds. Additionally, sensitivities of other postural algorithms often were reported based on the likelihood of a posture or activity being detected [13–15], rather than second by second analysis of the total collection duration. There have been

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Table 1
Tasks used for validation of acceleration classification.

Task	Description	Duration (s)
First protocol – static and dynamic tasks		
Jumping	Perform three consecutive standing jumps	5
Quiet standing	Subject stands on two feet	15
Quiet sitting	Subject sits down in a chair and remains seated	15
Walking	Subject stands up and walks at a self-selected pace	30
Jogging	Subject jogs at a self-selected pace	20
Stair climbing	Subject walks up and down a 7 step staircase	30
Walking	Subject walks at a self-selected pace	20
Jogging	Subject jogs at a self-selected pace	15
Lying down	Subject lies down supine, left, prone and right for 15 s each	60
Quiet sitting	Subject sits on the floor cross-legged or straight-legged	15
Standing	Subject stands up and is asked to sway/shuffle feet slightly	15
Sitting	Subject sits in a chair and fidgets legs and arms as if working at a desk	15
Second protocol – walking speeds		
Walking	Subject asked to walk across a 10 m walkway at self-selected slow, comfortable, and fast walking speeds.	600

no previous validation studies that included a wide range of walking speeds, postural transition detection, or detection of fidgeting while sitting and standing.

For accurate detection of postural transitions, walking, and jogging from body accelerations, wavelet transforms provide a better representation of the signal complexity than Fourier transforms. Building on a previously validated methodology [16], the current study provides algorithms for postural detection while including daily activities such as fidgeting while sitting or standing, transitions, and a range of walking speeds. Using wavelet transforms, it is possible to determine the changing frequency content over time on a non-stationary signal [17]. By representing the signal as a sum of a scaled and time shifted mother wavelet, wavelet transforms have previously demonstrated their utility in obtaining transition and gait pattern information [17,18]. In this study, we utilize continuous wavelet transforms (CWT) to identify slow walking instants.

A robust method for classifying postural orientation and movement needs to be established that can be applied to healthy and patient populations. Therefore, the purpose of this study was to develop and validate an algorithm for the identification of static postures and dynamic movement from acceleration data against visual inspection from video recordings in the laboratory. Specifically, the utility of tri-axial accelerometers in detecting static orientations of standing, sitting and lying down as well as dynamic movements of walking, jogging and transitions was assessed for validity and reliability. Identification of walking and jogging was further assessed over a range of gait velocities.

2. Materials and methods

2.1. Experimental design

This investigation included 12 healthy adults (9 females; median (range) age of 31 (25–55) years; average (SD) body mass index (BMI) of 24.7 (5.5) kg/m²), who were free of musculoskeletal deficits, neurological impairment or lower extremity surgery. Subjects were asked to perform two experimental protocols. During the first protocol, an approximately 5 min series of static postures and dynamic movements were conducted, consisting of sitting, standing, lying, walking, jogging and stair climbing in the laboratory (Table 1). Additionally, during a portion of the sitting and standing tasks, subjects were asked to ‘shuffle’ their body to simulate changing body position or fidgeting during sitting and standing tasks. An investigator provided verbal cues for performing each task.

For the second protocol, in order to test the ability of the algorithm to accurately detect postures and movements at a range of gait speeds, subjects were asked to walk across an 8.5 m walkway

at 7–10 self-selected slow, medium and fast speeds. During each trial, photocells placed on either end of the walkway recorded the subject's walking duration, with walking velocity calculated based on the distance traversed and the time duration. Following each trial, subjects were asked to walk at a slower or faster speed, in order to obtain a range of gait speeds.

2.2. Data collection

Static orientations and dynamic movement was recorded using a hand held video camera and activity monitors. The video camera collected data at 60 Hz, with an investigator ensuring that the subject remained within the capture volume throughout the experiment. Custom built activity monitors, developed at the Mayo Clinic, collected acceleration data at 100 Hz. Each sensor contained a tri-axial MEMS accelerometer (analog, $\pm 16g$, Analog Devices), microcontroller (12 bit ADC, Texas Instruments), power source (Tadiran battery, semiconductor voltage regulator), and onboard data storage (NAND flash memory, 0.5 GB memory chip, Micron). Accuracy of the accelerometers was determined to be within $\pm 0.56\%$. Two activity monitors, each weighing 22 g with dimensions of 4.7 cm \times 2.8 cm \times 1.2 cm, were donned on subjects on a waist band on the pants between the two ASIS and on the lateral mid-point of the right thigh. Monitors were oriented such that the y-axis pointed vertically. The x- and z-axes were directed in the anterior and lateral directions for the waist; and in the lateral and posterior directions for the thigh. The study protocol was approved by the Mayo Clinic Institutional Review Board and written informed consent was obtained from all research participants prior to beginning data collection. Video data were synchronized to the accelerometer data by asking all subjects to perform three vertical jumps prior to performing the described protocol. The two accelerometers were also synchronized to each other based on the onset of jumping. Prior to data collection, both accelerometers were calibrated to record +1g, 0g and –1g when placed in orthogonal orientations.

2.3. Movement detection

Prescribed postures and movements performed by the research participants during the protocol were analyzed and identified (Fig. 1). Accelerometer analyses were performed using custom MATLAB programs (MathWorks, Natick, MA). Acceleration signals from the waist accelerometer were used to differentiate dynamic activity from static postures. In order to remove any high-frequency noise spikes, a median filter with a window size of 3 was applied to each of the three orthogonal raw acceleration signals [16]. The resulting filtered signal was separated into its

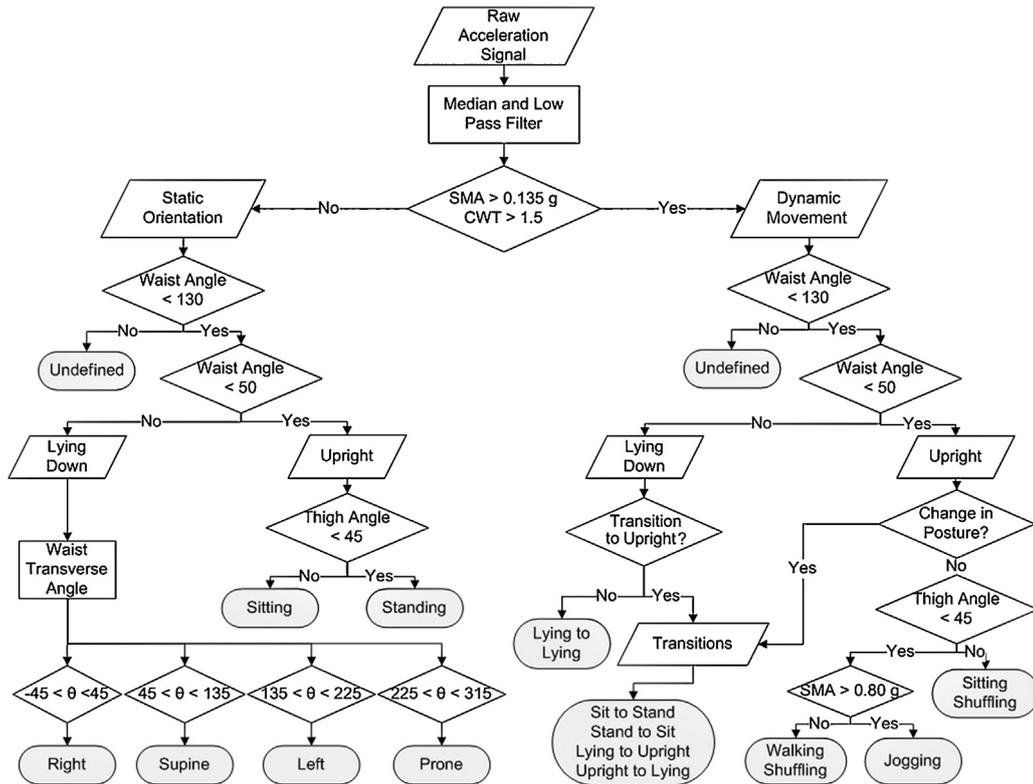


Fig. 1. Decision algorithm for the possible posture and activity classifications determined from the accelerometer data. SMA refers to the signal magnitude area and CWT to the continuous wavelet transform.

gravitational component by using a third-order zero phase lag elliptical low pass filter, with a cut-off frequency of 0.25 Hz, 0.01 dB passband ripple and -100dB stopband ripple. Subtracting the gravitational component from the original median filtered signal provided the bodily motion component.

The gravitational and bodily motion components of the acceleration signal were used to identify all possible outcome configurations (Fig. 2). The bodily motion component was utilized in determining static versus dynamic activity, with signal magnitude area (SMA) values above a threshold of 0.135g identified as movement [19]. The signal magnitude area was computed over each 1 s window (t) across all three orthogonal axes (a_x, a_y, a_z) (Eq. (1)).

$$SMA = \frac{1}{t} \times \left(\int a_x(t)dt + \int a_y(t)dt + \int a_z(t)dt \right) \quad (1)$$

Of those seconds of data identified as non-movement (i.e. or those seconds below 0.135g), a continuous wavelet was utilized [20]. The Daubechies 4 Mother Wavelet was applied in this study on the waist acceleration signal. Data which fell within a range of 0.1–2.0Hz was further identified as movement, if it exceeded a scaling threshold of 1.5 over each second. The wavelet toolbox in Matlab was used to calculate the wavelet transforms.

2.4. Postural orientation

The gravitational component of the signal provided the tilt angle over all three orientations (θ, φ, α) for the device [16]. Both the waist and thigh accelerometer orientations were used to identify postures (Eq. (2)).

$$\theta = \arccos\left(\frac{a_x}{g}\right); \quad \varphi = \arccos\left(\frac{a_y}{g}\right); \quad \alpha = \arccos\left(\frac{a_z}{g}\right) \quad (2)$$

Lying down was determined when the absolute value of the vertical waist angle was between 50° and 130°, with undefined orientations defined for waist angles greater than 130° and upright postures between 0 and 50°. Among upright postures, standing and sitting were differentiated based on the thigh angle, in relation to gravity, of less than 45° or greater than 45°, respectively [21]. To differentiate lying conditions between supine, prone, left and right positions, the waist angles in transverse plane were portioned into four equal 90° segments [16].

2.5. Dynamic classification

Among dynamic portions of data, the orientation of the waist again indicated whether an individual was sitting, lying down or upright on both feet. Rolling over while lying down was classified as a transition, specifically lying to lying. For the remaining transitions of upright to lying, lying to upright, sit to stand or stand to sit, beginning and ending segments of lying and sitting were identified. If a different orientation (lying, sitting, and standing) was identified up to 2 s prior to and 2 s after the beginning and ending points, the appropriate transition was labeled for the active seconds of postural change. Among upright movement, sitting while fidgeting was identified by the thigh angle. Walking and jogging were differentiated among the remaining upright movements based on a threshold of 0.80g for the SMA. The walking category included stair climbing, level walking, and portions of standing while fidgeting.

Thresholds for static and dynamic classification were determined based on observations made on a single random subject prior to complete validation on the remaining participants, with chosen values similar to those previously utilized [16,21]. Initial thresholds were based on algorithms previously reported [16], with visual

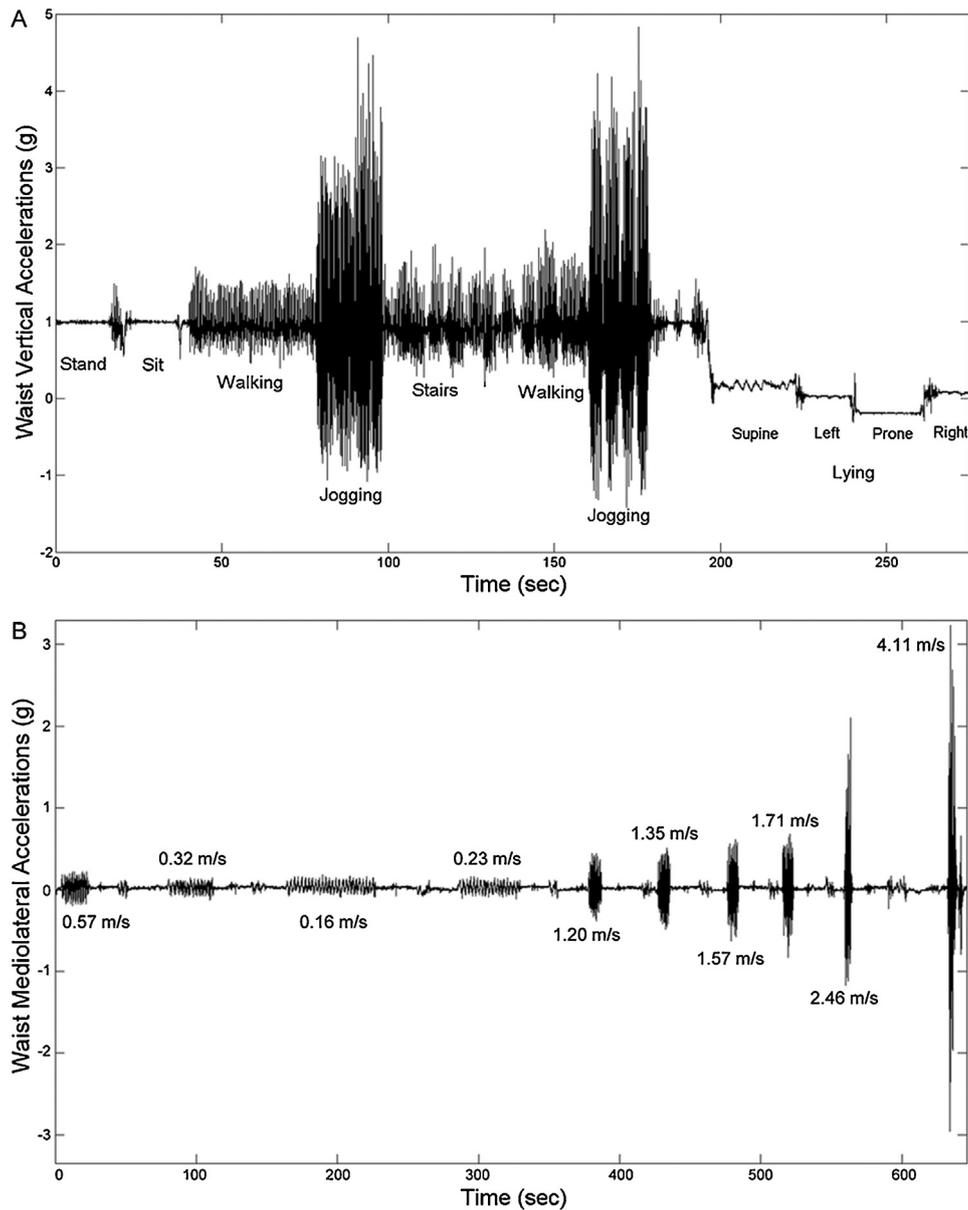


Fig. 2. Sample data of the waist accelerations ($g = 9.81 \text{ m/s}^2$) collected for a subject while performing a series of tasks (A) and walking at a range of gait speeds (B).

optimization performed for modification of the orientation values and SMA thresholds.

2.6. Reliability

Video data were imported into Windows Movie Maker (Microsoft, Seattle, WA). Two raters, each with greater than one year of gait analysis experience, determined the starting and ending times for each static orientation and movement. The video data were considered the gold standard for all validation analysis. Classified data were organized into 1 s windows for the video data. Reliability of inter-rater video observations were determined using intraclass correlations across all subjects for the total time spent in each posture or movement (ICC) (A,1) [22]. Fidgeting while sitting and standing was categorized as activity by video observers.

2.7. Validity

Validity of the accelerometer algorithm to properly identify different postures and movement was assessed with sensitivity and positive predictive value. Similar to the video classification, accelerometer data were organized into 1 s windows. Sensitivity described the percentage of an observation category which was correctly detected by the accelerometers, or the ratio of true positives to the sum of true positives and false negatives. Positive predictive value (PPV) provided the percentage of true positives that was identified when compared to the total number of true positives and false positives determined by the accelerometers. The sensitivity and PPV were considered substantial when greater than 60% and almost perfect when greater than 80% [24]. In a recent study, a sensitivity of 71.7% and specificity of 67.8% were classified to be acceptable for detecting sitting postures in healthy children [25]. The Bland–Altman method was utilized to compare the total

Table 2
Duration spent in each task and the intraclass correlation coefficient (ICC) for two raters.

Task	Rater 1 (s) ^a	Rater 2 (s) ^a	ICC ^b
Dynamic movement ^c	175 (18)	178 (18)	0.96 (0.80, 0.99)
Walking	109 (13)	107 (13)	0.95 (0.82, 0.99)
Jogging	34 (4)	35 (5)	0.94 (0.55, 0.99)
Transitions	31 (5)	34 (7)	0.47 (−0.04, 0.80)
Standing	57 (13)	56 (13)	0.96 (0.86, 0.99)
Sitting	61 (13)	61 (13)	1.00 (0.99, 1.00)
Lying	63 (6)	61 (6)	0.92 (0.65, 0.98)

^a Values provided are the mean and standard deviation.

^b Values provided are the ICC (A,1) along with the lower and upper bounds for the 95% confidence interval [22].

^c Dynamic movement included walking, jogging and transitions.

time spent in each posture or movement type as determined by both the accelerometers and video observation [26].

3. Results

All twelve participants completed the protocol as prescribed, with complete acceleration traces acquired for eleven subjects (Fig. 2). For one individual, the waist accelerometer came loose during the laying down transitions, and therefore all subsequent analyses during the first protocol for this subject were not utilized.

3.1. Reliability

The total time to complete the first protocol averaged 359 ± 42 s, with further discrimination of movement demonstrating only slight differences between the two observers for most postures (Table 2). Reliability of video observation was high, with ICC values greater than 0.95 for all postures and activity, except for transitions. Video identification of transition had ICC values of 0.47, indicating differences between the two raters in identifying lying to lying, upright to lying, lying to upright, sit-to-stand, and stand-to-sit transitions. All further analyses were performed comparing accelerometer identification to a single observer.

3.2. Validity

Only the waist accelerometer was required to accurately detect onset of movement. The addition of the thigh monitor allowed for identification of sitting postures. The current algorithm did not provide a means for discriminating stair climbing from level walking. The results of a second-by-second comparison of accelerometer data to rater identification of different tasks demonstrated median sensitivities above 98% for static orientations of sitting and lying down (Fig. 3A). A greater number of false positives were detected for standing, as accelerometers categorized fidgeting while standing as movement, with the identification of standing having sensitivity values of 86%. Among dynamic orientations, walking and jogging were accurately identified, with median sensitivities of greater than 96%. Second-by-second transition identification demonstrated a median sensitivity of 87%. Average positive predictive values were greater than 80% for all static and dynamic orientations, except for standing and transitions (Fig. 3B). Transitions demonstrated the lowest positive predictive values, with a median value of 71%. When fidgeting tasks were excluded, the

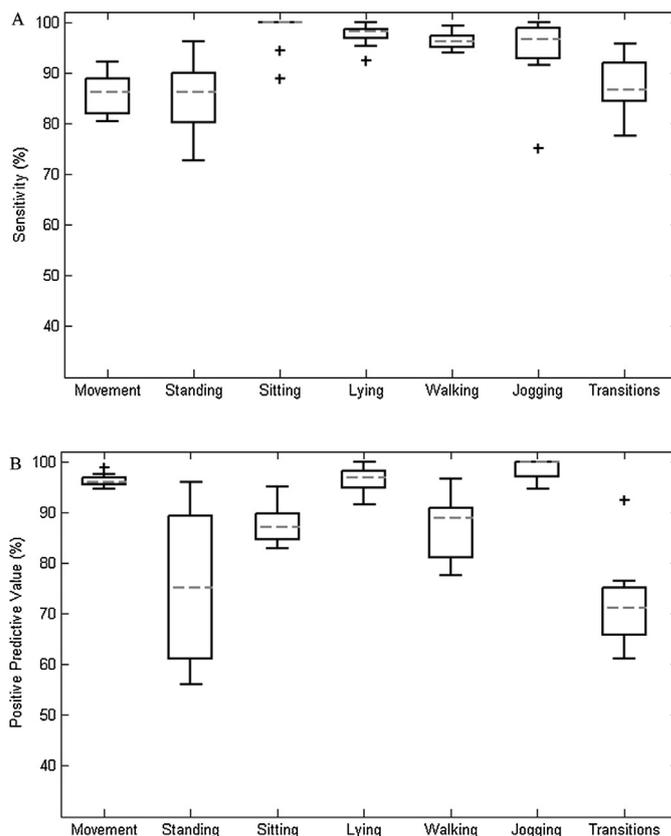


Fig. 3. Sensitivity (A) and positive predictive value (B) when identifying static orientations and dynamic movements with accelerometer data compared to video identification among all subjects. The central line represents the median, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to ± 1.5 of the interquartile range. Outliers beyond this range are labeled as '+'. For the PPV of jogging, the median value is equal to 100%.

positive predictive values of static standing and transitions increased to 85%.

The false positive lying orientations that were incorrectly identified by the accelerometer occurred during the fidgeting while sitting task, as individuals would orient themselves such that the waist accelerometer assumed a supine lying stature. False negatives occurred at the beginning or end of the lying tasks, with the accelerometer identifying these seconds as transitional. Among the lying positions, supine, prone, left or right lying orientations were correctly identified at greater than 98% sensitivity and 94% PPV across all subjects.

The amount of time spent in each static or dynamic task demonstrated substantial agreement, when utilizing the Bland–Altman method to compare the accelerometer to video observation (Fig. 4). Larger differences were demonstrated for standing, once again reflective of interpretation in the fidgeting tasks. Transition times were often identified as different static or dynamic task at the start or end of some tasks resulting in greater discrepancy during these seconds of transition. Additionally, waist accelerations did not reach the predetermined threshold for jogging in one individual. By jogging and walking at similar speeds, incorrect identification of the jogging task led to a single subject falling outside the 1.96 SD range for both movements. Among transitional standing tasks, individuals often took small steps, turns or other slight movements as they awaited instruction. While video observation listed these fidgeting seconds as static standing, the accelerometer would identify these times as activity if the SMA reached the predetermined threshold.

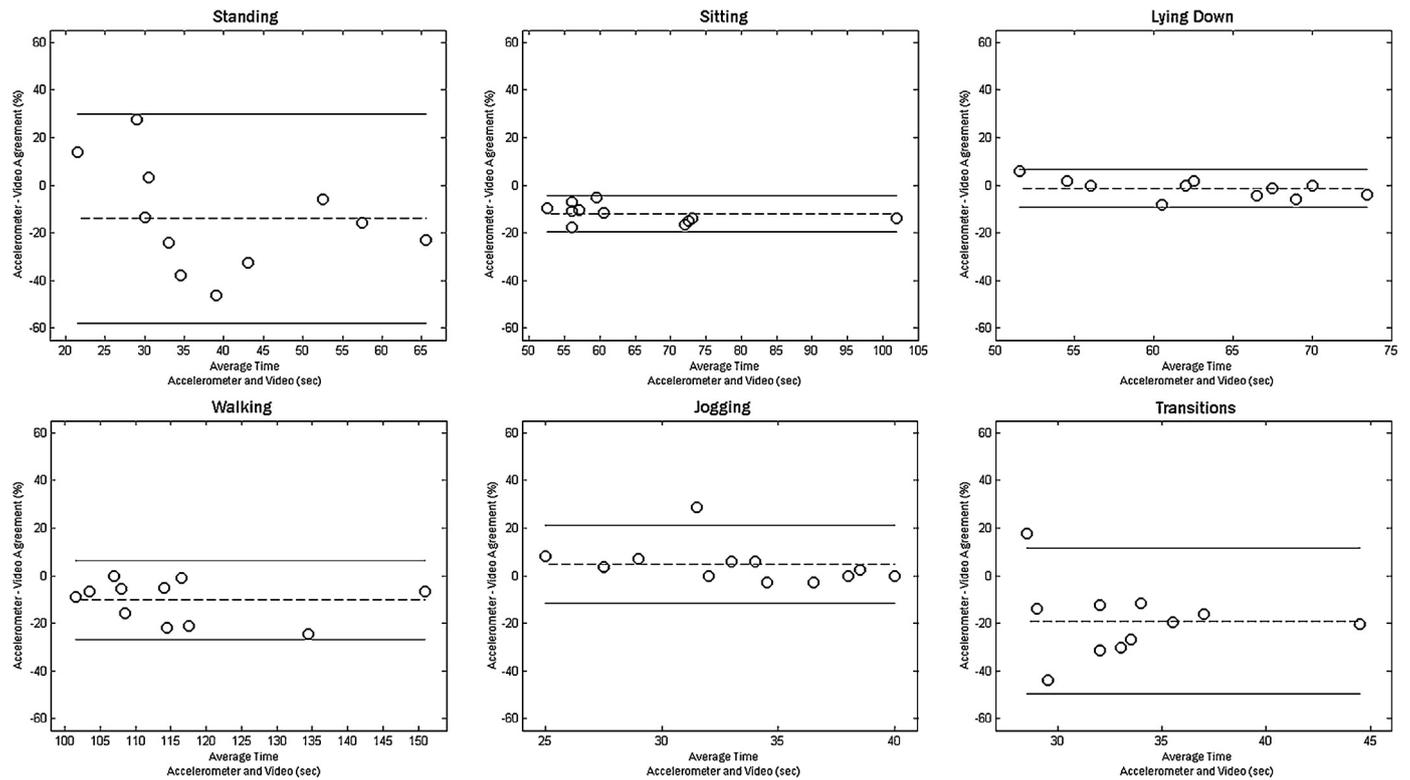


Fig. 4. Bland–Altman plots demonstrating error in identifying each of the static and dynamic activities when using accelerometer compared to video identification. The data for each of the 12 subjects studied includes fidgeting while sitting or standing. The dashed line is the average, while the solid lines represent the repeatability coefficient (± 1.96 SD).

Utilizing a combination of SMA and wavelet transform thresholds, walking was accurately detected at speeds ranging from 0.1 and 4.8 m/s (Fig. 5). Most discrepancies occurred at the endpoint seconds of activity segments, thereby reducing the sensitivity of faster walking segments which were completed in a short duration. During the outlier trials, subjects additionally performed stutter steps at the beginning of the trial, with investigators not identifying these seconds as movement.

4. Discussion

The purpose of this study was to develop and validate an algorithm using accelerometers to classify static postures and dynamic movement. Additionally, accuracy of these devices to recognize movement was quantified over a range of tasks, gait velocities, and

realistic daily activity such as fidgeting while sitting and standing. Utilizing two accelerometers allowed for accurate assessment of static and dynamic orientations. Tri-axial accelerometers attached to the waist and thigh can therefore be utilized to accurately track individuals in the free-living environment. The ability to identify movement at slow velocities below 1.0 m/s can allow for accurate detection among adults and patients with slow walking velocities [7].

While previous studies have utilized one accelerometer to detect posture and movement [10,27], the use of a second monitor attached to the thigh can provide greater accuracy in discriminating weight bearing and non-weight bearing activities [28,29]. Additionally, the use of a 16g accelerometer can allow for proper assessment of an extensive range of daily physical activity, including possible fall event detection [29,30].

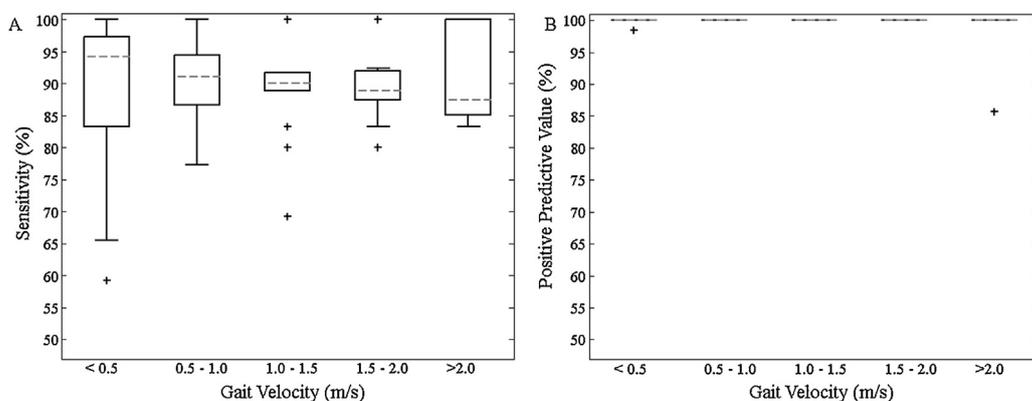


Fig. 5. Boxplot of activity detection when walking at a range of gait velocities. The median sensitivity (A) was greater than 84% and the median PPV (B) 100% at all velocities. The central line represents the median, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to ± 1.5 of the interquartile range. Outliers beyond this range are labeled as '+'

Inter-rater reliability was almost perfect, with ICC values greater than 0.92, when comparing all video observations except for poor reliability during transitions between postures or activities. ICC values for standing, sitting and walking are comparable to previous results, in which walking, sitting, standing, and lying ICCs were found to be 0.95, 0.78, 0.99 and 0.98, respectively [10,31]. Inter-rater reliability of transitions has not been previously reported. Discrepancies between observers occurred due to differences in the frame selection at the beginning or end of postures. Rater selection of transition times was therefore variable. Since the variance and length of time spent in transition was small, the ICC values also became smaller with any differences observed [32]. Variable observer identification can therefore affect accuracy values for posture and movement.

While incorrect identification of movement and posture could lead to under- or overestimation of intervention efficacy among clinical populations, the current algorithm demonstrated a valid detection of movement and posture. Among the subjects tested, median sensitivity and positive predictive values of static posture, walking, and jogging classification was greater than 85%.

These results are superior to or similar to those previously reported for other accelerometer based activity monitors [16,21,33], where walking, standing, sitting and lying demonstrating agreement ranging from 65.1 to 98.9% during a fixed protocol and 68.3–85.9% in the home environment [10]. While average sensitivities across subjects were adequate, some subjects demonstrated reduced sensitivity during the standing posture. For these subjects, fidgeting during stance and imprecise monitor placement due to body habitus resulted in decreased accuracy of the accelerometer identification. Subjects were asked to don the waist monitor below the navel, and discrepancies in the vertical orientation of the monitor produced tilt angles of greater than 0° when standing upright due to excessive adipose tissue. When standing, lying or sitting, these angles often became exaggerated, with incorrect identification of the static orientation occurring across several seconds.

The use of SMA to distinguish walking from other activity has demonstrated good sensitivity and specificity [20]. While such analysis has previously been utilized to detect movement during self-selected walking speeds of healthy adults, it cannot accurately recognize movement among slower walking adults. By using wavelet transforms, the ability to identify slow walking is additionally accomplished in this study, with high accuracy down to 0.1 m/s. By detecting slow gait velocities, it becomes possible to accurately quantify walking in older adults and patients. No studies to our knowledge have investigated walking detection at slow gait velocities, though high accuracy of step counting has been reported for speeds between 0.90 m/s and 1.84 m/s when walking over ground and on a treadmill [34]. Investigating slow walking speed is of clinical importance, as of those older adults who walk at less than 0.25 m/s, only 36% are independent in all ADL functions [7]. Increasing gait velocity beyond 0.55 m/s increases ADL functionality, with adults walking faster than 1.0 m/s demonstrating good functional status and better survival rates [7,8,35].

Distinguishing higher physical activity such as jogging was further enabled in this study using the SMA threshold of 0.80g. This threshold allowed for accurate detection and discrimination between walking and jogging. A previous study that utilized the ratio of the unfiltered to filtered acceleration as well as the filtered vertical to filtered horizontal accelerations at the waist demonstrated the ability to discriminate locomotive tasks from household tasks [27], but identification of walking, jogging, and stair climbing activities was not demonstrated.

Any inaccuracy in classification of standing, sitting, and walking was due to fidgeting tasks, window size resolution, and task duration. All subjects were asked to perform sitting and standing

tasks for approximately 15 s while fidgeting to recreate motions produced by individuals when fidgeting at the desk or while standing. Such high frequency, short-duration walking behavior was previously demonstrated by nondisabled adults over the course of a 2-week period [36]. While some subjects in our study voluntarily moved only slightly, greater motions resulted in reduced sensitivities for some subjects. When assessing non-fidgeting sitting and standing tasks, classification accuracy increased beyond 85%. Not including fidgeting tasks, classification errors occurred only at the beginning or end of each activity. These differences can be attributed to segmentation of both the accelerometer and video data to 1 s windows.

Greater resolution in window size would presumably provide even greater accuracy. Mathie and colleagues suggested window width around 1 s, consistent with the timescale of human movement, though a smaller window size might provide added optimization [19]. In our study, certain transitions and standing activities were observed to take under 1 second during video analysis. Such quick activity might have added to the errors seen in the transitional periods.

The duration of the tasks in this study was limited to between 15 and 30 s per segment. With longer duration tasks, greater accuracy can be achieved, as misclassification commonly occurs during the 1 s at the beginning or end of a task. Greater accuracy is expected for long duration postures using the current algorithm, with studies demonstrating an accuracy of 80% for longer duration tasks in both the laboratory and home environment setting [10,33]. In a previous study investigating posture in elderly adults over the course of 4 days, accuracy of sitting, standing and lying was found to be 92%, 98%, and 95%, respectively, using 1 min windows [33]. The use of fidgeting, slower walking speeds in this study, and the ability to accurately identify movement in all subjects allows for a robust algorithm. As 40% of walking bouts last 12 steps or fewer [36], fidgeting and short duration tasks were of importance in this study. While longer duration tasks allow for greater accuracy, short duration tasks typically seen in the free-living environment could lead to reduced accuracy. While other authors have further discounted movement that lasted less than 5 s [12], all transitions and short duration movements were included in the current analysis.

A limitation of this study is the current inability to differentiate stair climbing from level walking. While further analysis will investigate the differences in these two tasks, it is noted that subjects in the current study were ambulating at similar speeds when walking and stair climbing, with upright locomotion activity properly identified. A second limitation is the lower accuracy in detecting transitions. While identification was poorer for this activity, sensitivity and PPV results still exceed 70%. Utilizing video observation as a gold standard can also be subjective and error prone, as demonstrated by discrepancies in identifying transitions between raters.

While accelerometer based identification utilizes objective measures, raters often identify end points of posture and motion inconsistently, resulting in many of the inaccurate findings throughout the study. While validation was performed in a laboratory setting, the algorithm will be further tested for real-time processing in a free-living environment. The strength of this study is in the inclusion of a range of body types (BMI range of 19.9–40.1 kg/m²) with a less constrained testing procedure that includes more natural movements, such as fidgeting during static postures, and a range of gait speeds.

5. Conclusion

Results of this study suggest that the use of accelerometers can accurately detect static postures and dynamic movement among the general population. The ability to identify static and dynamic

tasks as well as at a range of gait velocities can allow for accurate classification of all adults in the home living environment.

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Conflict of interest

The authors report no conflict of interest.

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Validity of using tri-axial accelerometers to measure human movement – Part II: Step counts at a wide range of gait velocities



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ABSTRACT

A subject-specific step counting method with a high accuracy level at all walking speeds is needed to assess the functional level of impaired patients. The study aim was to validate step counts and cadence calculations from acceleration data by comparison to video data during dynamic activity. Custom-built activity monitors, each containing one tri-axial accelerometer, were placed on the ankles, thigh, and waist of 11 healthy adults. ICC values were greater than 0.98 for video inter-rater reliability of all step counts. The activity monitoring system (AMS) algorithm demonstrated a median (interquartile range; IQR) agreement of 92% (8%) with visual observations during walking/jogging trials at gait velocities ranging from 0.1 to 4.8 m/s, while FitBits (ankle and waist), and a Nike Fuelband (wrist) demonstrated agreements of 92% (36%), 93% (22%), and 33% (35%), respectively. The algorithm results demonstrated high median (IQR) step detection sensitivity (95% (2%)), positive predictive value (PPV) (99% (1%)), and agreement (97% (3%)) during a laboratory-based simulated free-living protocol. The algorithm also showed high median (IQR) sensitivity, PPV, and agreement identifying walking steps (91% (5%), 98% (4%), and 96% (5%)), jogging steps (97% (6%), 100% (1%), and 95% (6%)), and less than 3% mean error in cadence calculations.

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1. Introduction

Physical inactivity is an independent risk factor for chronic disease and disability and is estimated to result in 3.2 million deaths world-wide each year [1]. Regular physical activity has been associated with health improvements in many populations [2]. Many commonly used mobility assessment methods have limitations such as subjectivity [3] or involve clinical-based evaluations that fail to mimic real-world functional requirements, such as the 10 m walk test which underestimates gait velocity predictions in a community setting [4]. It is important to quantitatively assess mobility in the free-living environment as health and wellness measure. This can be accomplished with accurate measurement of step counts and cadence in the home and community.

Step counting is one of the most commonly used measures of physical activity [5]. Sensors can provide objective information on movement while their small size and light weight allow for home deployment. One of the main issues associated with step counts as a

physical activity measure is that high accuracy is needed. Many previous studies have assessed the step count and gait event accuracy of pedometers, accelerometers, and gyroscopes [6–11]. However, limited information on the algorithms and the data analysis methods are provided and the protocols performed are overly simplified, often consisting of long periods of continuous walking which are inconsistent with most daily living activities. The step detection accuracy of many sensors has also been shown to decrease for shorter activity duration and at slower walking speeds [8,12–14], particularly in older patients. The need for accurate step counts at slow walking speeds is of critical importance as slow walking speeds can be indicative of movement disorders [15], mobility disability [16], and have been linked to high risk for reduced function, morbidity, and mortality [17]. Increases in walking speed and the ability to vary cadence demonstrate increased function level [18], reduced risk, and higher predictions of survival [17,19]. While a small number of studies have shown that results from the methods they used are not affected by different walking speeds, accuracy during shuffling, stair climbing, and jogging have yet to be investigated and only limited gait velocity ranges are examined [14,20,21]. Furthermore, the use of step counts as a measure of physical activity is limited as the characteristics of the steps are unknown. An activity monitoring system (AMS) capable of identifying walking step counts, jogging step counts, and the ability to vary cadence while walking and jogging can be beneficial as it gives information on an individual's functional level. Furthermore, an objective

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portable method for the functional assessment of patients, particularly those with slow walking speeds, could serve as a beneficial motivational rehabilitation tool and an effective clinical outcomes measure in the free-living environment.

The aim of this study was to determine the validity and reliability of a custom-designed AMS as an objective adaptive step counter. The algorithm's accuracy was validated with visual step counts and was compared to two commercial step counters (Fitbit Tracker (Fitbit, San Francisco, CA) and Nike+ Fuelband (Nike, Beaverton, OR)) during walking and jogging trials at a range of gait velocities. The validity and reliability of the AMS algorithm were also evaluated for walking and jogging segments in healthy adults during a protocol of simulated free-living dynamic activities in the laboratory by comparison to video recordings.

2. Materials and methods

2.1. Experimental design

Accelerometer and video data were acquired from 12 (3 M, 9 F) healthy adults as they performed 7–10 walking/jogging trials in a straight line over an 8.5 m walkway (with additional room to accelerate and decelerate). Subjects wore two different commercial devices (Fitbit monitors on the right lateral ankle and the waist and a Nike Fuelband on the right wrist) in addition to the AMS which consisted of accelerometers below the navel on the waist, on the right thigh lateral midpoint, and bilateral ankles. Gait velocities were calculated based on the distance travelled and the time duration recorded by photocells placed at either end of the walkway. For the initial trial, subjects were asked to walk at a self-selected normal gait velocity. Following each trial, subjects were given instructions to walk/jog at a slower/faster speed, until a suitable range of gait velocities was obtained. The steps were counted visually by two raters. A total of 105 trials were recorded in total. Accelerometer and video data were also recorded as subjects performed an approximately 5 min protocol of static and dynamic activities involving standing, sitting, lying, postural transitions, walking, stair climbing, and jogging in the laboratory [22]. Verbal cues were provided by an investigator for each task. Additionally, subjects were asked to fidget to simulate activity during selected sitting and standing tasks. All activities were performed at self-selected speeds. At the time of evaluation, the subjects' median (range) age and average (SD) body mass index (BMI) were 31 (25–55) years, and 24.7 (5.5) kg m⁻², respectively. Exclusion criteria were a history of musculoskeletal deficits, neurological impairment, or lower extremity surgery. The study protocol was approved by the Mayo Clinic Institutional Review Board and each subject provided written informed consent before participating.

2.2. Data collection

The AMS consisted of four Mayo Clinic custom-built activity monitors which were secured with straps. Each activity monitor incorporated a tri-axial MEMS accelerometer (analog, ±16 g, Analog Devices), and onboard data storage of up to 0.5 GB [22]. Monitors were programmed to sample each axis at 100 Hz. Video data were simultaneously acquired at 60 Hz using a handheld camera. Video data were synchronized to accelerometer data by three vertical jumps performed by subjects prior to and following the described protocol. The four accelerometers were also synchronized to each other after the final jump.

2.3. Signal processing

Step numbers and heel-strike timings for AMS step detection were determined from the bilateral ankle activity monitors

(Fig. 1). All accelerometer data post-processing and analysis were performed offline using MATLAB (Version 7.11.0, Mathworks, Natick, MA). A median filter, with a window size of 3, was applied to the orthogonal raw acceleration signals to remove any high-frequency noise spikes. The resulting filtered signal was separated into its gravitational component using a third-order zero phase lag elliptical low pass filter, with a cut-off frequency of 0.25 Hz, 0.01 dB passband ripple and –100 dB stopband ripple. Subtracting the gravitational component from the original median filtered signal provided the bodily motion component [23].

2.4. Activity detection

In a parallel study by the authors [22], dynamic activity was detected by calculating when the signal magnitude area (SMA) of the bodily motion component of the waist accelerometer data exceeded a threshold of 0.135 g [24] for epochs of 1 s. Of those seconds of data (which were below 0.135 g) identified as non-activity, a continuous wavelet transform using a Daubechies 4 Mother Wavelet was applied to the waist acceleration signal. Data which fell within a range of 0.1–2.0 Hz was further identified as activity, if it exceeded a scaling threshold of 1.5 over each second [22]. Upright activity was identified using the angles estimated from the waist and thigh accelerometers. Activity was characterized as jogging when the SMA exceeded 0.8 g and as walking (including stair climbing and fidgeting of the feet while standing) when the SMA was between 0.135 and 0.8 g. The threshold of 0.8 g was determined from this dataset [22], based on comparisons of SMA to video data for a single subject and validated across all subjects.

2.5. Step detection

During identified walking and jogging segments, the antero-posterior accelerations (a_{AP}) of the ankles were filtered using a low-pass butterworth filter with a cut-off frequency of 6 Hz and analyzed using a peak detection method [9] with adaptive a_{AP} thresholds similar to those previously formulated for angular velocity [20] and an adaptive timing threshold to calculate the number of steps taken (Fig. 1).

Gait events, gait velocity, and cadence are useful when describing normal and pathological gait [25]. Step counting methods are often based on toe-off, heel-strike, and/or midswing identification with defined absolute thresholds determining the acceleration values these gait events must reach and how much time must lapse between consecutive gait events to identify valid steps [9]. As gait velocity, cadence, and swing phase usually decrease with increasing disability, the gait event accelerations also decrease and the time between gait events increases [25]. These parameter changes can cause accuracy issues when using absolute thresholds to assess subjects with slower/pathological gait velocities. Even within-subject gait velocity changes can reduce accuracy, i.e. walking slowly while performing household chores, may result in activity underestimation [26]. To overcome these issues, our algorithm incorporates adaptive thresholds for acceleration and time between gait events.

2.5.1. Calculate initial adaptive thresholds (Fig. 1b)

The adaptive peak detection thresholds allow for greater step detection accuracy at different walking speeds. For each continuous data segment classified as walking or jogging, adaptive a_{AP} thresholds to detect heel-strike points were calculated,

$$th_1 = 0.8 \times (1/N) \times \sum_{i=1}^N a_{AP_i} < \bar{a}_{AP} \quad (1)$$

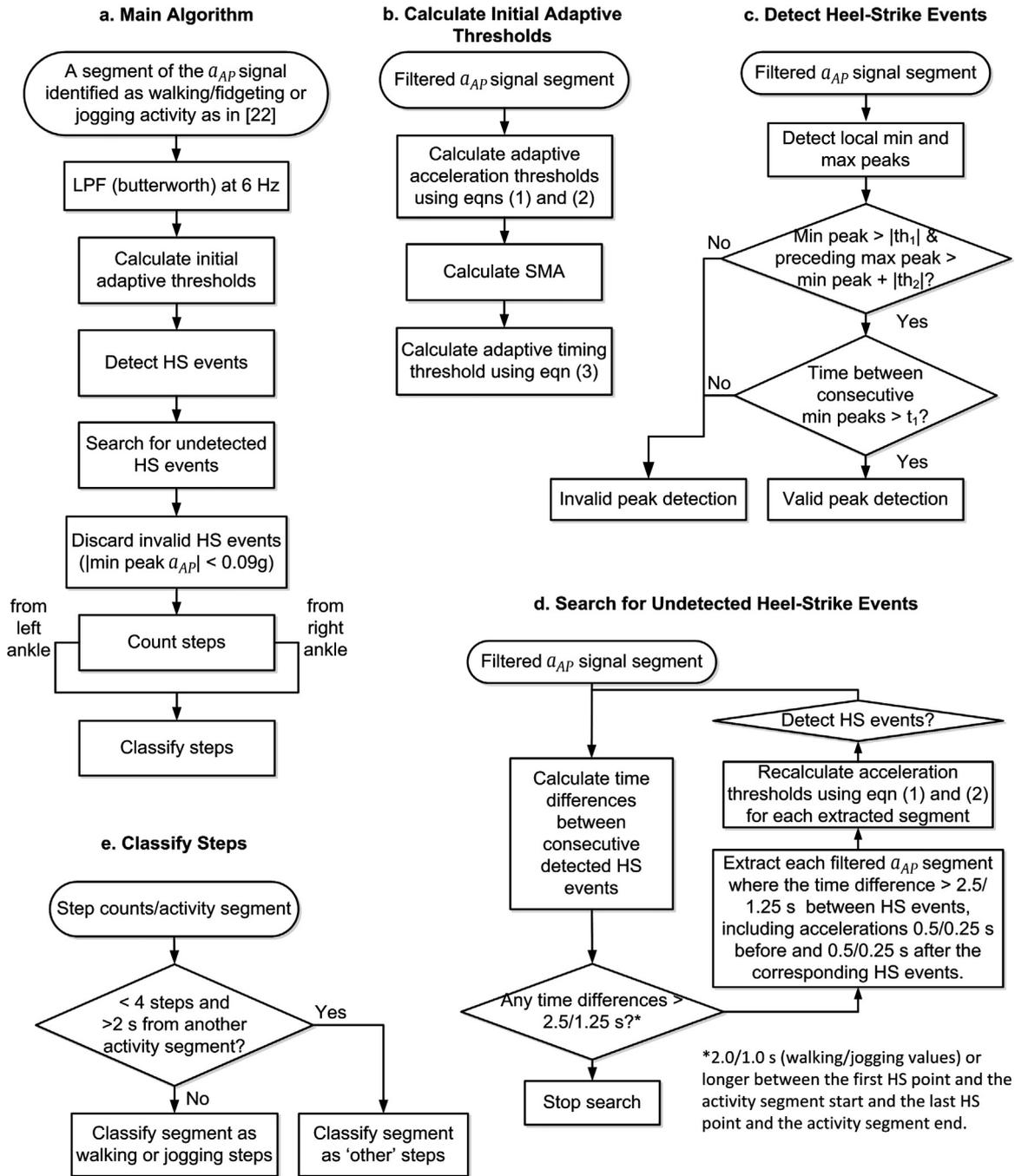


Fig. 1. Flowchart of the step detection algorithm applied to the acceleration values of each segment of dynamic activity detected from the postural and activity detection algorithm. (a) Shows the main stages of the algorithm, (b)–(e) describe the algorithm in additional detail. HS: heel-strike, LPF: low pass filter, a_{AP} : anteroposterior acceleration.

where \bar{a}_{AP} is the mean of the a_{AP} signal and N is the number of samples,

$$th_2 = 0.6 \times \min(a_{AP}) \quad (2)$$

In addition to adaptive a_{AP} thresholds, adaptive timing thresholds were also calculated. The timing threshold, t_1 , was calculated for each walking segment using

$$t_1 = f_s \times 0.1 / \text{mean}(\text{SMA}) \quad (3)$$

where f_s is the sampling frequency and SMA is the signal magnitude area of the waist. A minimum value for t_1 was set at 0.5 s.

2.5.2. Detect heel-strike events (Fig. 1c)

Local minimum and maximum peaks of the a_{AP} signal were detected. Local minimum peaks were considered valid heel-strike points if their magnitudes were greater than $|th_1| g$, and had a preceding maximum whose magnitude was at least $|th_2| g$ greater than the minimum. If two minimum peaks were found within t_1 s of each other for walking and 0.25 s of each other for jogging, only the one of greater amplitude was considered as a heel-strike point.

2.5.3. Search for undetected heel-strike events (Fig. 1d)

Adaptive thresholds do not work well when high heel-strike acceleration variability occurs. In order to address this issue of activity with high heel-strike acceleration variability (particularly

during walking segments which included stair climbing), the algorithm was extended to check for missing steps in each segment of data by calculating the time difference between each successive heel-strike point. For walking/low frequency walking (detected using the wavelet transform), if there was a time interval of 2.5/8 s or longer between successive heel-strike points (2.0/7.5 s or longer between the first heel-strike point and the start of the activity segment and the last heel-strike point and the end of the activity segment), the acceleration thresholds (Eqs. (1) and (2)) were recalculated for the segment of data within 0.5 s from either heel-strike point and new heel-strike points were looked for within that segment. For jogging, if the time interval was 1.25 s or longer between successive heel-strike points (1 s or longer between the first heel-strike point and the start of the activity segment and the last heel-strike point and the end of the activity segment), the acceleration thresholds were recalculated for the segment of data within 0.25 s from either heel-strike point and new heel-strike points were sought within that segment.

2.5.4. Discard invalid heel-strike events

Activity monitor acceleration readings are accurate to within 0.09 g. Therefore, any heel-strike points with a_{AP} magnitudes less than 0.09 g were discarded.

2.5.5. Count steps

For each activity segment, steps counts from both the right and left ankle acceleration data were summed.

2.5.6. Classify steps (Fig. 1e)

To identify walking or jogging steps from other less meaningful steps such as fidgeting, a previous study ignored any activity which lasts for less than five seconds [27]. However, discarding five second activity segments in this study could mean ignoring as high as 15 steps per activity segment. Another study recommended discounting steps if less than two steps with the right leg occur in a ten second window and no steps occur in the ten second windows on either side [28]. Applying this method to the present study resulted in the classification of all fidgeting and walking segments with less than four steps were classified as 'walking' which resulted in an overestimation in walking step counts. In this study, any segments with less than four steps total detected from the right and left ankles which were preceded and followed by more than two seconds of no activity were not considered as walking or jogging and their steps were categorized as 'other'. The two seconds threshold was chosen to account for possible activity classification errors at the first and last one second epochs of activity segments [22]. This characterization was also applied to video observation.

2.5.7. Calculate cadence

Cadence was calculated from

$$\text{Cadence} = (n - 1)/(t_n - t_1) \quad (4)$$

where n is the total number of steps in the activity segment, t_n is the time (min) when the heel-strike point of the n th step occurs and t_1 is the time (min) when the heel-strike point of the first step occurs.

2.6. Reliability

Video data were imported into Windows Movie Maker (Microsoft, Seattle, WA). Two raters, each with greater than one year of gait analysis experience, manually determined the walking, jogging and 'other' step counts for each activity. The video data were considered the gold standard for all validation analysis. Intraclass

correlations (ICC(A,1)) across all subjects were used to determine the reliability of inter-rater observations [29].

2.7. Validity

AMS algorithm step counts were validated against the steps counted manually from the video data for each subject. Agreement is the percentage of steps detected using the AMS algorithm compared with those counted manually from the video data. Sensitivity is the ratio of true positives to the total number of true positives and false negatives. Positive predictive value (PPV) is the ratio of true positives to the total number of true positives and false positives. Heel-strike times (i.e. times at which the non-stance leg made contact with the floor) were visually identified to calculate cadence from the video data and sensitivity, PPV, and agreement were used to assess the AMS algorithm's ability to accurately detect steps. The AMS algorithm, Fitbits, and Nike Fuelband accuracies were compared using agreement values only.

The Bland-Altman and ICC(A,1) methods were utilized to compare step counts and cadence as determined by the AMS algorithm and video observation [30]. In the Bland-Altman plots, systematic error is present if the mean is greater than or less than zero. Systematic error is considered to be significant if both repeatability coefficients are on the same side of zero.

3. Results

Eleven of the twelve participants completed the protocol as prescribed. Data from one subject were excluded since the protocol was not followed correctly. The total time to complete the protocol of static and dynamic activities averaged (SD) 359 (42) s and the mean (SD) total number of steps taken was 282 (20).

3.1. Reliability

Inter-rater reliability of step detection using video observation was high, with ICC(A,1) values of 1 for the walking/jogging trials and greater than 0.98 for steps taken during walking, steps taken during jogging and the total number of steps taken throughout the simulated free-living protocol (Table 1). All further analyses were performed comparing AMS algorithm identification to a single observer chosen at random.

3.2. Validity

The AMS algorithm demonstrated a median (IQR) agreement of 92% (8%) with manual step counts as gait velocities ranged from 0.1 to 4.8 m/s compared with median (IQR) agreements of 92% (36%), 93% (22%), and 33% (35%) using Fitbit (ankle), Fitbit (waist), and Nike Fuelband (wrist), respectively (Fig. 2). The AMS algorithm median agreement was highest for gait velocities lower than 0.5 m/s (Table 2). The lowest median (IQR) agreements occurred between 1.0 and 1.5 m/s and 1.5 and 2.0 m/s, both at 89% (7%). For gait velocities ranging from 0.1 to 4.8 m/s, step counts were underestimated by a mean of 1.5 steps and there was no

Table 1
Inter-rater reliability for the 5 min protocol of static and dynamic activities.

Task	Rater 1 ^a	Rater 2 ^a	ICC(A,1) ^b
Walking	195.0 (16.4)	196.7 (17.1)	0.982 (0.919, 0.996)
Jogging	86.5 (13.7)	87.0 (12.6)	0.988 (0.956, 0.997)
All activity	281.5 (19.7)	283.7 (19.9)	0.981 (0.907, 0.995)

^a Average (SD) total step count for each activity as determined by two raters.

^b Values provided are the estimated ICC(A,1) with lower and upper bounds for the 95% confidence interval [29].

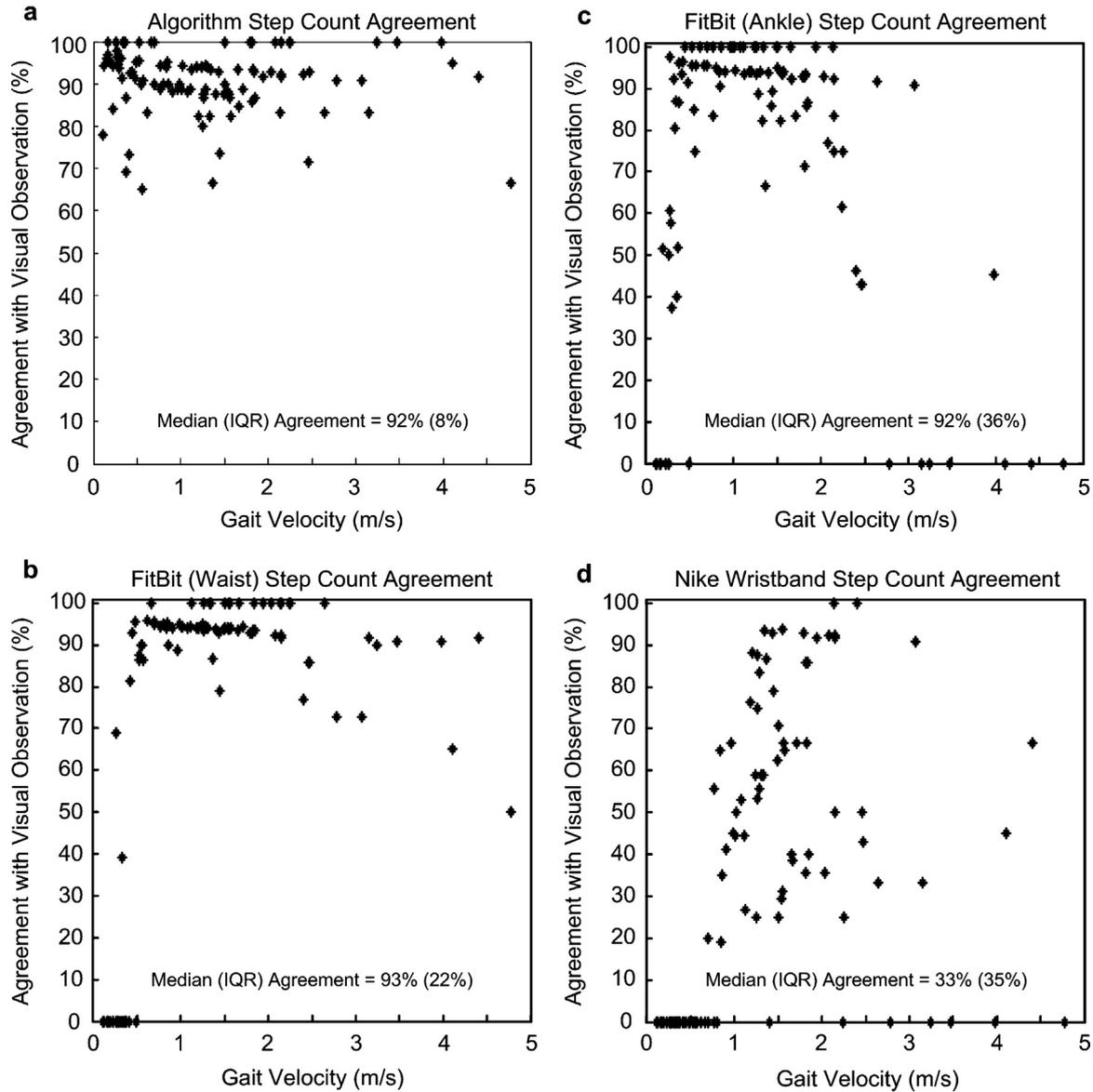


Fig. 2. Step count agreement with visual observations for (a) the activity monitoring system algorithm, (b) Fitbit located at the right lateral ankle, (c) Fitbit located at the waist, and (d) Nike Fuelband worn on the wrist as gait velocity ranges from 0.1 to 4.8 m/s.

significant systematic error (Fig. 3). The ICC(A,1) value was greater than 0.97. Four of the five outliers occurred at gait velocities less than 0.62 m/s due mostly to very low ankle peak a_{AP} as well as due to some seconds of activity not being detected. The fifth outlier occurred at approximately 1.25 m/s due to missed seconds of activity. The Fitbit demonstrated higher median agreement values than the AMS algorithm between 0.5 and 2 m/s but didn't detect steps for velocities less than 0.5 m/s when located on the waist and detected only approximately 50% of steps for velocities less than 0.5 m/s and greater than 2 m/s when located on the ankle.

Steps were detected for each upright dynamic activity segment during the protocol for each subject and were classified as walking (Fig. 4a and b), jogging (Fig. 4c), or other. Stair walking demonstrated high variability of peak accelerations (Fig. 4a). The number of steps taken for each segment ranged from 2 to 115. For the group, step detection median (IQR) sensitivity was 95% (2%) across subjects, with 91% (5%) for walking and 97% (6%) for jogging (Fig. 5a). The step detection median (IQR) PPV was 99% (1%) across subjects, with 98% (4%) for walking and 100% (1%) for jogging (Fig. 5b). The step detection median (IQR) agreement was 97% (3%),

Table 2

Median (IQR) agreement of algorithm, Fitbit (ankle), Fitbit (waist) and Nike Fuelband step counts compared with visual, and median (IQR) number of steps for different gait velocity ranges.

Gait velocity range (m/s)	<0.5	0.5–1.0	1.0–1.5	1.5–2.0	>2.0
Activity monitor (%)	95 (6)	90 (6)	89 (7)	89 (7)	92 (11)
Fitbit (Ankle) (%)	52 (91)	96 (6)	94 (11)	93 (7)	46 (85)
Fitbit (Waist) (%)	0 (0)	94 (5)	94 (1)	94 (7)	92 (16)
Nike Fuelband (%)	0 (0)	0 (41)	59 (33)	66 (47)	43 (91)
Number of steps	31 (14)	20 (4)	17 (2)	15 (1)	12 (5)

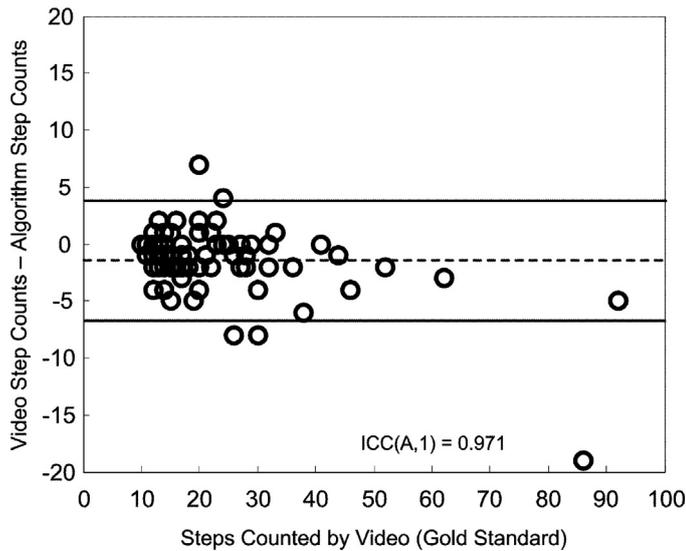


Fig. 3. Bland Altman plot demonstrating the difference between the activity monitoring system algorithm and visual step counts as the number of steps taken changes (as a result of changes in gait velocity). The dashed line is the mean, while the solid lines represent the repeatability coefficient (± 1.96 SD).

with 96% (5%) for walking and 95% (6%) for jogging. The step counts from the AMS algorithm showed good agreement when compared to video data (ICC(A,1) values greater than 0.75) except for steps classified as ‘other’ (ICC(A,1) value was 0.4) (Fig. 6). No significant systematic errors were present. Mean percentage errors were approximately 5% for all walking segments, 1% for the longest walking segment on level ground and stairs, 3% for the longest walking segment on level ground, 3% for all jogging segments, 4% for all activity combined and 63% for other. The median (IQR) sensitivity, PPV, and agreement, and ICC(A,1) values increased from 91% (5%), 98% (4%), 96% (5%), and 0.75 for all walking (Figs. 5a,b, and 6a) to 96% (2%), 99% (3%), 97% (2%), and 0.97 for the longest walking segment on both level ground and stairs (Figs. 5a,b, and 6b) and to 97% (4%), 100% (0%), 97% (5%), and 0.93 for the longest walking segment on level ground only (Figs. 5a,b, and 6c). The calculated mean cadences were 103 steps/min for walking on level ground, 102 steps/min for walking on level ground and stairs, and 155 steps/min for jogging. Correlations between video observation and AMS algorithm identification were high for cadence calculations (ICC(A,1) values greater than 0.82) and showed excellent agreement across all subjects for the longest walking segment on level ground, the longest walking segment on both level ground and stairs and the two jogging segments (Fig. 7). No significant systematic errors were present and mean percentage errors were less than 1% for walking on level ground (except for one outlier), 3% for the first jogging segment (except for one outlier), 2% for walking on level ground and stairs (except for one outlier), and 3% for the second jogging segment (except for one outlier).

4. Discussion

The study aim was to validate an algorithm using an AMS to measure step counts and cadence during walking and jogging for a wide range of gait velocities. There is a need for an accurate objective step counter for patients with slow walking speeds as they would benefit most from a motivational tool capable of accurately monitoring activity increases. The described step detection algorithm incorporates an adaptive acceleration threshold heel-strike detection algorithm capable of managing activity segments with high acceleration variability and includes adaptive timing

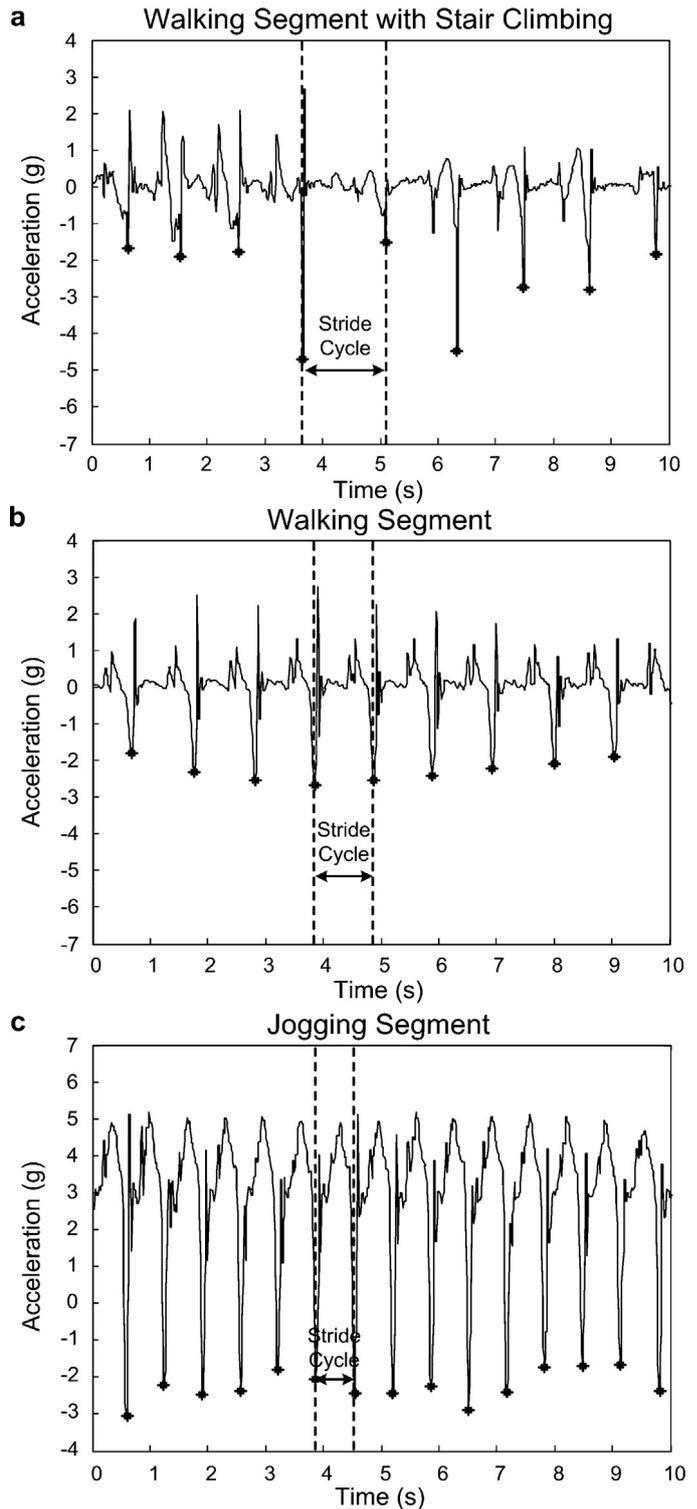


Fig. 4. Sample of 10 s duration of right ankle anteroposterior accelerations for one representative subject from the longest identified (a) walking (on flat ground and during stair climbing), (b) walking (on flat ground), and (c) jogging segments. Each heel-strike detected using peak detection with adaptive thresholds is denoted with an asterisk.

thresholds for robustness across a large gait velocity range. The step detection algorithm was used in combination with a postural and activity detection algorithm so that only upright dynamic activity was analyzed and to enable the data analysis of a protocol with a continuous flow of static and dynamic activities such as would occur in free-living.

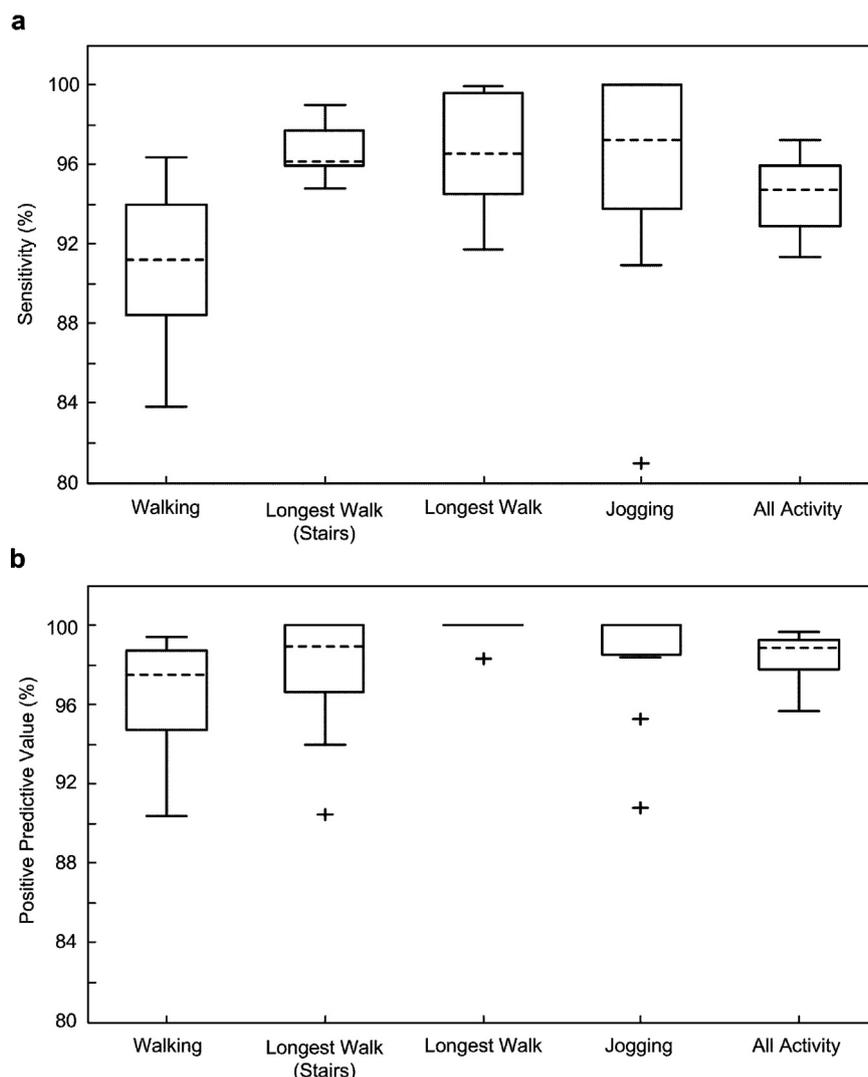


Fig. 5. Step detection sensitivity (A) and positive predictive value (B) when identifying all walking steps, walking steps during the longest activity segment which includes stair climbing, walking steps during the longest activity segment on flat ground only, jogging steps, and the total number of steps compared to video identification. The central line represents the median, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to ± 1.5 of the interquartile range. Outliers beyond this range are labeled as +. For the PPV of jogging, the median value is equal to 100%. For the PPV of the longest walking segment on level ground, the median value, the 25th and 75th percentiles are equal to 100%.

The small discrepancies between the two video raters (Table 1) were due to subjective differences in deciding which steps taken during fidgeting could be classified as valid steps and deciding when the activity switched between walking and jogging. With some subjects, step counts were less accurate, mostly due to small inaccuracies of walking and jogging segment detection at the beginnings and ends (walking detection median (IQR) sensitivity was 87% (7%) and PPV of 95% (3%), while jogging detection median (IQR) sensitivity was 97% (7%) and PPV of 100% (2%)) [22], resulting in one or more missing steps. These inaccuracies can be attributed to the segmentation of both the accelerometer and video data to one second windows when identifying dynamic upright activity.

For gait velocities from 0.1 to 4.8 m/s, the AMS algorithm detected steps with a higher median agreement and/or smaller IQR than the Fitbits and Nike Fuelband (Fig. 2 and Table 2). Furthermore, Fitbit does not incorporate postural detection and may overestimate steps in free-living from leg movement during sitting and lying in addition to upright posture. Nike Fuelband agreement was poor across all velocities and also includes no postural detection. Previous studies have also reported difficulties in obtaining accurate step counts at slow and high walking speeds [8,14,31,32]. A

small number of studies report good accuracy for all walking speeds [14,20,21,31]. However, many of these studies do not specify gait velocities and refer to them as 'slow, normal, or fast-paced', while studies that specify gait velocities look at smaller ranges starting at 0.5–0.9 m/s [14,32] and don't exceed 2 m/s. Studies using the Step-watch activity monitor (SAM) to detect strides and activity levels in stroke patients and elderly adults have reported good agreement ranging from 'acceptable' to 'excellent' with visual step counts at gait velocities as low as 0.08 m/s [33,34]. However, SAM requires two one minute calibration walk tests at self-selected normal and fast walking speeds for each patient in the laboratory prior to testing in a free-living environment. Calibration tests are repeated until SAM shows at least 94% agreement with visual counts.

The lowest median agreement in this study occurred between 1.0 and 2.0 m/s which is the typical range of normal walking speeds [35], while the highest agreement occurred for velocities lower than 0.5 m/s and higher than 2 m/s (Table 2). Steps taken ranged from 10 to 92, increasing as gait velocity decreased. Similar to previous studies, longer duration trials (i.e. trials where gait velocity was less than 0.5 m/s) demonstrated greater agreement as missed steps usually occur at activity segment ends [13]. At higher gait

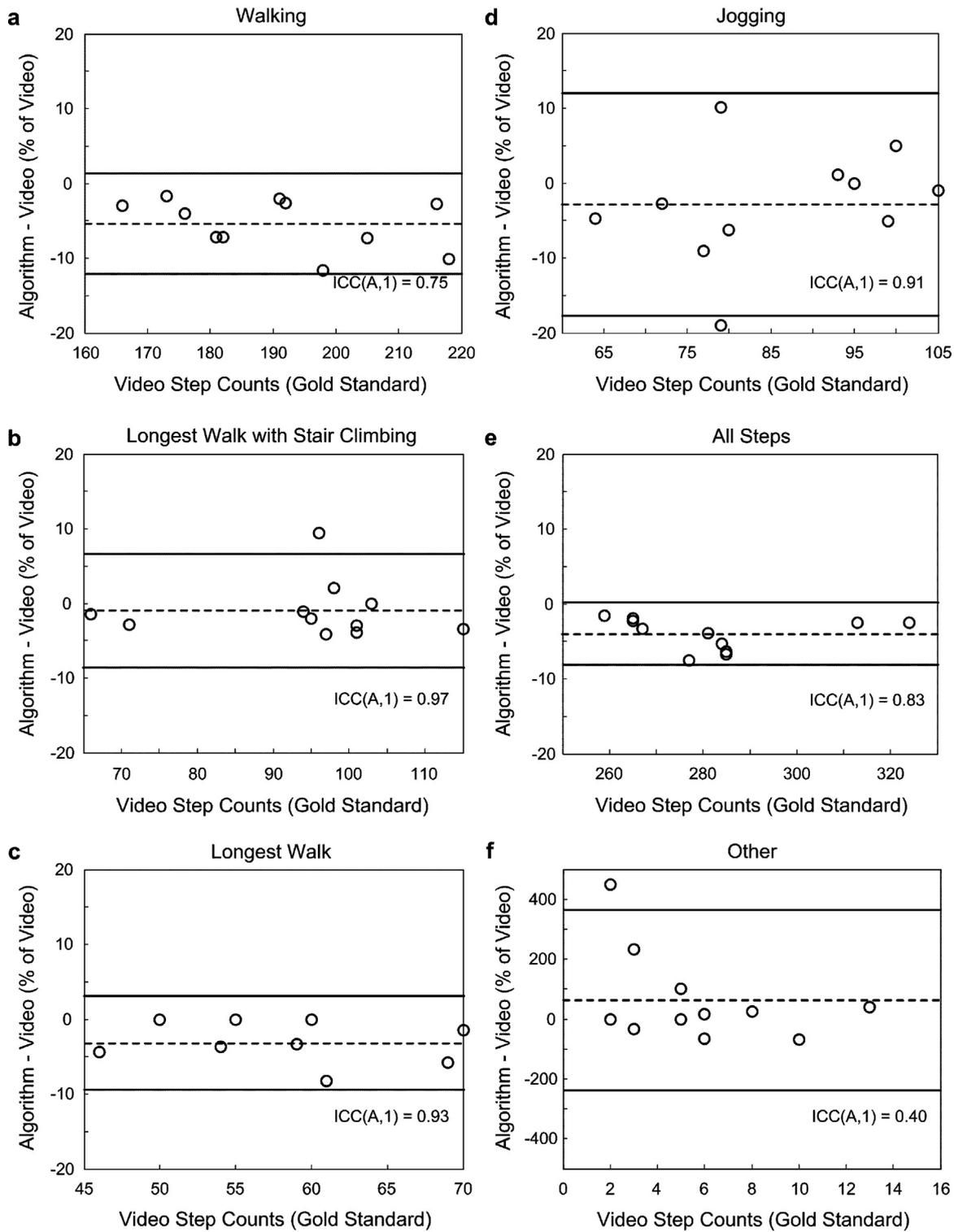


Fig. 6. Bland-Altman plots demonstrating percentage difference for step detection when using activity monitoring system algorithm and video identifications for (a) walking, (b) walking during the longest activity segment including stair climbing, (c) walking during the longest activity segment on level ground only, (d) jogging, (e) the entire protocol, and (f) all steps classified as ‘Other’. The dashed line represents the mean, while the solid lines represent the repeatability coefficients (± 1.96 SD). ICC(A,1) values are also presented.

velocities, peak acceleration amplitudes increased in magnitude and decreased in magnitude variability, resulting in increased step detection accuracy, particularly at gait velocities higher than 2 m/s. The ability of the AMS algorithm to accurately detect steps for less than 0.5 m/s suggests that it would be a beneficial outcome measures tool for rehabilitating patients with slow walking speeds.

The 3% mean agreement difference from manual step counts (Fig. 6e) was due mostly to activity segments with fidgeting of the feet while standing or with less than 4 steps. The lower step detection accuracy when considering all walking was due to the inclusion of very short walking segments (Fig. 6a). The slightly higher step detection accuracy when considering walking on both level ground

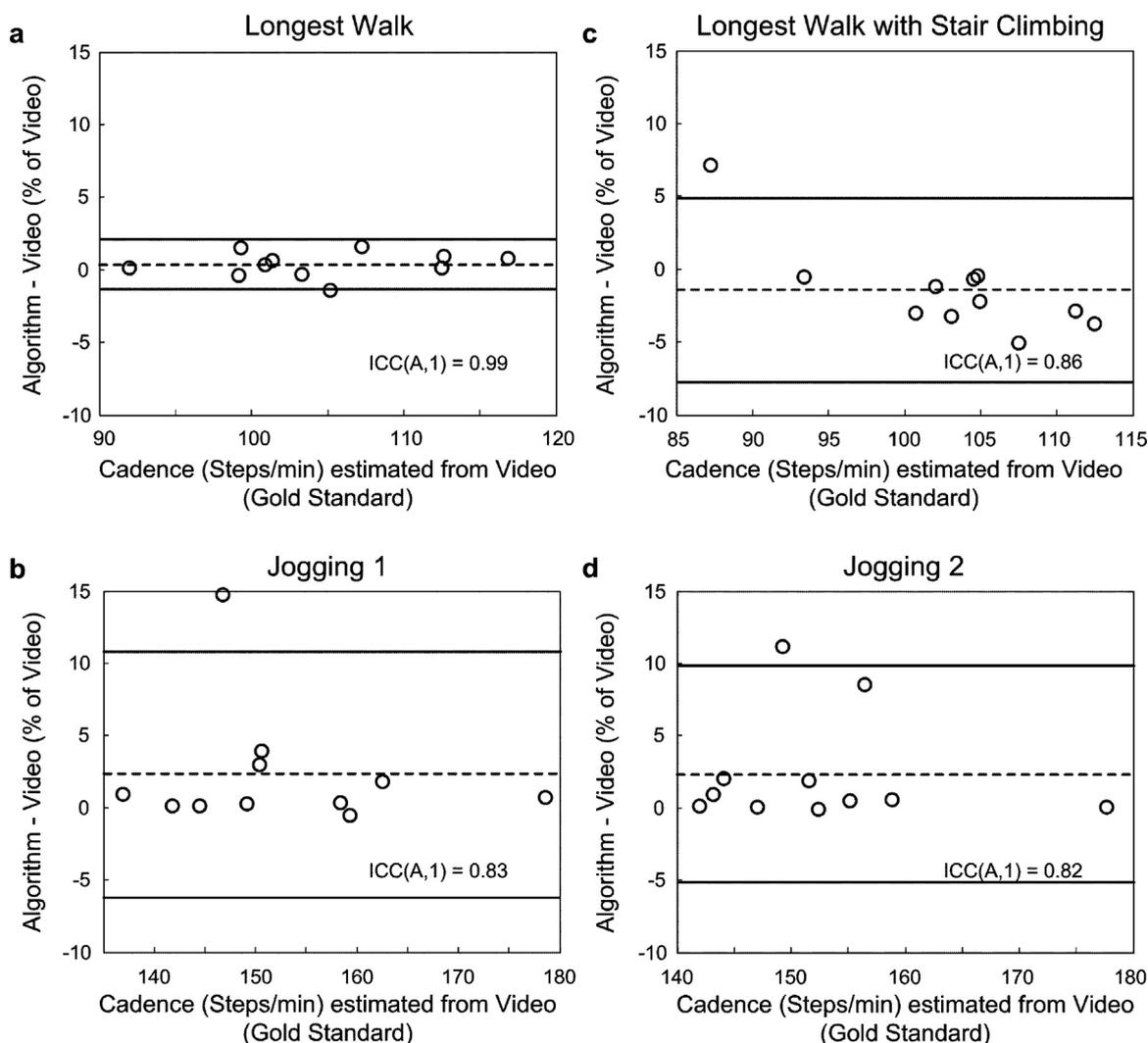


Fig. 7. Bland-Altman plots demonstrating percentage difference for cadence when using activity monitoring system algorithm and video identifications for (a) the longest walking segment on level ground, (b) the first jogging segment, (c) the longest walking segment including stair climbing, and (d) the second jogging segment. The dashed line represents the mean, while the solid lines represent the repeatability coefficients (± 1.96 SD). ICC(A,1) values are also presented.

and stairs (Fig. 6b) compared to level ground only (Fig. 6c) was also due to segment length. Step detection accuracy would be expected to increase for longer walking and jogging segments as the inaccuracies occur mostly at the segment's beginning and end, consistent with previous studies on step detection and activity classification [13,27,36]. A small number of studies have produced slightly higher agreement values (at gait velocities >0.8 m/s) than the step detection results in this study, however they involved activity segments which were isolated and much longer in length [14,37].

The calculated mean cadences for walking and jogging were consistent with previous studies on walking and jogging of healthy adults at a self-selected speed [38,39]. The mean percentage cadence calculation errors (Fig. 7) are comparable to results from a recent accelerometry study involving real-time cadence calculation during the 5 m walk test [12]. In the current study, the small cadence calculation errors were due to missed steps. Cadence variability has been shown to be an important factor when assessing patient function levels [18]. The most accurate pedometers can give step counts within $\pm 3\%$ of the manual step count, with step counts being classed as 'acceptable' when within $\pm 10\%$ [6,40,41]. The 97% median step count agreement value in this study when compared to video step counts and high agreement of cadences suggest that this method would be suitable for counting walking and jogging

steps using tri-axial accelerometers placed on the waist, thigh, and bilaterally on the ankles in a free-living environment. However, it is possible that other daily living activities not examined in this study may inhibit step detection accuracy. The advantage of using accelerometers for step counting, rather than traditional pedometers, is that it can also provide data such as gait event timings, amplitudes, and other spatiotemporal parameters. Accelerometers use less battery power than gyroscopes, making them more suitable for home deployment studies.

Stair climbing activity could not be identified separate to walking on level ground as the SMA/second calculations showed no distinguishable differences. However, the results presented here suggest that walking and stair climbing activity levels were similar and counting stair climbing steps as walking steps is sufficient for assessing activity using step counts. Previous studies have shown that the energy expended walking down stairs is similar to slow walking on level ground [42] and a third of that expended walking upstairs [43]. It is important to note that patient compliance issues have been reported in previous studies due to multiple sensor use which can be cumbersome for long-term data collections [44,45]. While accurate step counts can be used to effectively assess the functional status of impaired individuals, factors such as behavior and environment should also be considered in healthy individuals.

Conducting this study in a free-living environment would be more realistic but more difficult than in a laboratory. Many validation studies have used simplified laboratory-based testing methods (standing or sitting still or continuous periods of walking [8,24,41]). We instructed subjects to perform activities as naturally as they could, i.e. standing while moving their feet as standing completely still is not expected in a free-living environment [26], and switching between activities such as walking to sitting down and fidgeting of the body and/or legs. In addition, the laboratory space included stairs, a chair, and a bed. Only 12 healthy subjects were included in this study. While many studies use similar subject numbers [12,32,36], algorithm robustness should be tested on a larger subject number before applying it to the general population and also be validated before use in pathological or elderly populations. Each subject walked/jogged approximately 300 m during the protocol. While this is short compared to daily distances travelled in the community, it is similar to the distance tested in many studies [9,14,41]. Furthermore, as we tested a range of walking durations (activity segments of 2–115 steps), an overall longer duration of activity may not have a large effect on step detection accuracy. Another study limitation is that fidgeting was misclassified as walking in subjects that moved their feet a lot while standing. Some short walking segments were misclassified as 'other' if steps at the segment's beginning and end were undetected, resulting in an AMS algorithm step count of less than four. This contributed to lowering walking and 'other' step detection accuracy (Fig. 6a and f). The poor accuracy for detecting 'other' steps was also due to short activity duration resulting in missed steps and to the subjectivity of visually identifying fidgeting. A recent study also reported difficulty in fidgeting detection in the home with accelerometry methods and video observation [26]. However, the advantage of the method presented here is that adaptive acceleration and timing thresholds allow for use on a wide range of gait velocities and, therefore, potentially a wide range of patient populations and ages.

5. Conclusion

While this study involves a simulated protocol conducted in a laboratory environment, the results suggest that the proposed analysis methods are suitable for step counting using tri-axial accelerometers on the ankles, thigh, and waist in a free-living environment.

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Posture and Movement Classification: The Comparison of Tri-Axial Accelerometer Numbers and Anatomical Placement

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Patient compliance is important when assessing movement, particularly in a free-living environment when patients are asked to don their own accelerometers. Reducing the number of accelerometers could increase patient compliance. The aims of this study were (1) to determine and compare the validity of different accelerometer combinations and placements for a previously developed posture and dynamic movement identification algorithm. Custom-built activity monitors, each containing one tri-axial accelerometer, were placed on the ankles, right thigh, and waist of 12 healthy adults. Subjects performed a protocol in the laboratory including static orientations of standing, sitting, and lying down, and dynamic movements of walking, jogging, transitions between postures, and fidgeting to simulate free-living activity. When only one accelerometer was used, the thigh was found to be the optimal placement to identify both movement and static postures, with a misclassification error of 10%, and demonstrated the greatest accuracy for walking/fidgeting and jogging classification with sensitivities and positive predictive value (PPVs) greater than 93%. When two accelerometers were used, the waist-thigh accelerometers identified movement and static postures with greater accuracy than the thigh-ankle accelerometers (with a misclassification error of 11% compared to 17%). However, the thigh-ankle accelerometers demonstrated the greatest accuracy for walking/fidgeting and jogging classification with sensitivities and PPVs greater than 93%. Movement can be accurately classified in healthy adults using tri-axial accelerometers placed on one or two of the following sites: waist, thigh, or ankle. Posture and transitions require an accelerometer placed on the waist and an accelerometer placed on the thigh. [DOI: 10.1115/1.4026230]

Keywords: accelerometer, movement analysis, posture detection, monitor placement

1 Introduction

Developing tools to accurately assess posture and movement in a free-living environment is of great importance. However, many studies have reported patient compliance issues using activity monitors to assess physical activity in free-living environments [1–4]. One of the main issues which can affect patient compliance in assessments are requesting them to wear multiple sensors [5] which can be too cumbersome for long-term use [6]. Using numerous activity monitors per subject can provide information on the movement of a greater number of body segments. For more complex postural orientation and movement classifications, this can generate results of superior accuracy [2]. However, reducing the number of activity monitors would increase the user-friendliness of such assessments. This could increase participation willingness in activity assessments and reduce the possibility of user error [5] as instructions would be simpler.

In addition, patients may find some activity monitor placements to be uncomfortable which could further hinder patient compliance [5]. Optimal activity monitor placement and the number of activity monitors required depend greatly on the research question [7]. For whole body movement, locations on the waist, sternum

and lower back have been shown to be optimal, whereas thigh and ankle locations have been used to measure leg movement [8]. For more complex movement classification systems, higher numbers of activity monitors (up to 36) have been used [9,10]. Many different studies have demonstrated postural orientation and movement identification using varying numbers of activity monitors (from 1 to 7) and different locations [6,11–24]. However, only a few studies have investigated how the robustness of any of these postural and movement identification algorithms would change with different activity monitor numbers and locations [5,25,26]. Studies using one activity monitor for posture and movement identification utilize simplified protocols and whether or not the algorithms would perform as accurately for protocols involving fidgeting of the feet while sitting or standing has not been tested. Recently, a posture and movement classification algorithm was developed by the authors, which is capable of accurately identifying standing, sitting, and lying postures as well as walking, jogging, and transitional movement using two tri-axial accelerometers (one on the waist and one on the thigh) [27]. The study included a range of gait velocities from 0.1 m/s to 4.8 m/s and fidgeting of the legs while sitting and standing. An accurate posture and movement classification algorithm using either one or two accelerometers in a number of different locations would allow for user preferences of wear location and accelerometer numbers to be taken into consideration while providing a safeguard against missing data such as from malfunctioning devices.

The aim of this study were to determine and compare the validity of different accelerometer (1) placements and (2) combinations

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Table 1 Mean signal magnitude area and corresponding walking/fidgeting and jogging thresholds for different monitor locations

Variables	Ankle monitor	Thigh monitor	Waste monitor
Mean SMA for 5 min protocol (g)	0.584	0.355	0.296
Walking/Fidgeting threshold (g)	0.246	0.175	0.135
Jogging threshold (g)	1.46	1.04	0.8

for a previously developed posture and dynamic movement identification algorithm [27]. Three static postures and four dynamic tasks were recorded. The validity of the posture and dynamic movement identification algorithm for different accelerometer locations and combinations was evaluated in a simulated free-living environment by comparison to video recordings.

2 Methods

2.1 Experimental Design. The data used in this study was collected in a previous study [27] and reanalyzed for this study. Accelerometer and video data were acquired from 12 (3 M, 9 F) healthy adults as they performed an approximately 5 min protocol of static postures and dynamic movements involving standing, sitting, lying, walking, stair climbing and jogging in the laboratory [27]. Additionally, subjects were asked to make small movements of their body to simulate changing body position or fidgeting during selected sitting and standing tasks [27]. All activities were performed at self-selected speeds. At the time of evaluation, the median (range) age and average (SD) body mass index (BMI) of the subjects were 31 (25–55) years, and $24.7 \pm 5.5 \text{ kg m}^{-2}$, respectively. Exclusion criteria were a history of musculoskeletal deficits, neurological impairment or lower extremity surgery. The study protocol was approved by the Mayo Clinic Institutional Review Board and each subject provided written informed consent before participating.

2.2 Data Collection. Accelerometer data were captured from each subject using custom built activity monitors developed at the Mayo Clinic [27]. Each activity monitor incorporated a tri-axial MEMS accelerometer (analog, $\pm 16 \text{ g}$, Analog Devices), micro-controller (12 bit ADC, Texas Instruments), power source (Tadiran battery, semiconductor voltage regulator), and onboard data storage (NAND flash memory, 4 Gbit memory chip, Micron). Monitors weighed 22 gs with dimensions of $4.7 \text{ cm} \times 2.8 \text{ cm} \times 1.2 \text{ cm}$. Prior to data collection, all four accelerometers were calibrated to record $+1 \text{ g}$, 0 g and -1 g when placed in orthogonal orientations.

Subjects wore four activity monitors on the waist at the midpoint of the ASIS, on the lateral midpoint of the right thigh and bilateral ankles above the lateral malleoli. Activity monitors were secured with straps and were programmed to sample each axis at 100 Hz. Video data were simultaneously acquired using a handheld camera which collected data at 60 Hz. Video data were synchronized to the accelerometer data by asking all subjects to perform three vertical jumps prior to and following the described protocol. The four accelerometers were also synchronized to each other based on the onset of jumping. The onset of jumping was set as time zero for both video and accelerometer data. The time point for the onset of jumping was selected visually by a rater from the video data and manually from the acceleration data based on the onset of change in vertical acceleration of all the monitors. Three accelerometer placements and one accelerometer combination were analyzed in this study: (1) single waist, (2) single thigh, (3) single ankle, and (4) thigh and ankle (right side only) accelerometers. These configurations were compared to the previously analyzed and validated waist and thigh accelerometer combination [27]. The combination of the waist and ankle monitors was not

investigated in this study as it would not enable the separation of sitting and standing postures or the identification of sit to stand and stand to sit transitions. Therefore, this accelerometer combination would provide no additional information on postural and movement detection compared to using either the waist or ankle accelerometers alone apart from separating lying and sitting with legs straight, i.e., sitting up while in bed.

2.3 Signal Processing. All post processing and analysis of accelerometer data were performed offline using MATLAB (Version 7.11.0, Mathworks, Natick, MA, USA). The raw accelerometer data were calibrated and a median filter, with a window size of three, was applied to each of the orthogonal raw calibrated acceleration signals to remove any high-frequency noise spikes [15]. The resulting filtered signal was separated into its gravitational component by using a third-order zero phase lag elliptical low pass filter, with a cut-off frequency of 0.25 Hz, 0.01 dB passband ripple and -100 dB stopband ripple. Subtracting the gravitational component from the original median filtered signal provided the bodily motion component [15].

2.4 Movement Detection. Dynamic movement was detected by calculating when the signal magnitude area (SMA) of the bodily motion component of the accelerometer data exceeded the dynamic movement threshold (Table 1) for each 1 s interval [27]. In order to allow the identification of movement at lower frequencies (i.e., walking at gait velocities less than approximately 0.5 m/s) which are often missed when looking at SMA alone, a continuous wavelet transform (CWT) using a Daubechies 4 Mother Wavelet was applied to the acceleration signal over the frequency range of 0.1–2.0 Hz [28] for those seconds of data identified as nonmovement using SMA. The energy contribution for each data point was calculated from the coefficients returned from the CWT using a scalogram. If the average energy contribution for a 1 s interval exceeds 1.5, that 1 s interval is classified as dynamic movement. The value of 1.5 was determined based on observations made on a single random subject (as it gave the greatest agreement of detected seconds of movement with video-observed seconds of movement at slow gait velocities) prior to complete testing on the remaining subjects. The wavelet toolbox from MATLAB was used to calculate the wavelet transforms in this study. Movement was characterized as jogging when the SMA exceeded the jogging threshold (Table 1) and as walking (including stair climbing and fidgeting of the feet while standing) when the SMA was between the threshold for dynamic movement and jogging. The threshold of 0.135 g for dynamic movement detection from waist accelerations was obtained from Ref. [29] and the threshold of 0.8 g for jogging detection for waist accelerations was obtained from Ref. [27]. The thresholds for detecting dynamic movement and jogging from acceleration data recorded from the thigh and ankle were calculated as ratios of the waist acceleration thresholds (Eq. (1)) as both thigh and ankle accelerations were consistently larger than waist accelerations during movement (Fig. 1). These ratios were determined from the mean of the signal magnitude area (SMA) from each monitor location from the 5 min simulated free-living protocol for all subjects (Table 1).

$$th_{\text{monitor location}} = \frac{\text{mean}(SMA_{\text{monitor location}})}{\text{mean}(SMA_{\text{waist}})} \times th_{\text{waist}} \quad (1)$$

where $th_{\text{monitor location}}$ is the threshold for either movement or jogging at a specified accelerometer location, i.e., thigh or ankle.

2.5 Postural Orientation. When using a single waist or ankle accelerometer, lying down was determined when the waist or ankle angle was between 50 and 130 deg, with undefined orientations for waist or ankle angles greater than 130 deg and upright postures between 0 and 50 deg (Fig. 2(a)) [30]. When using only

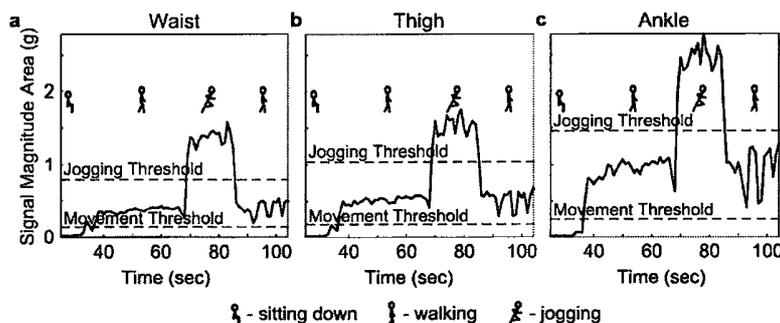


Fig. 1 Mean signal magnitude area per second and corresponding movement and jogging thresholds for (a) waist, (b) thigh, and (c) acceleration data from one subject chosen at random during the simulated free living protocol

the thigh accelerometer, standing and sitting/lying were differentiated based on the thigh angle, in relation to gravity, of less than 45 deg or greater than 45 deg, respectively [30] (Fig. 2(b)). To differentiate lying conditions between supine, prone, left and right positions, the angles in transverse plane were portioned into four equal 90 degree segments [15]. When using both the thigh accelerometer with the ankle accelerometer, the ankle accelerometer was used to detect movement and to determine if the posture was upright or lying down while the thigh accelerometer was used to determine if upright postures were standing or sitting (Fig. 2(c)). Rolling over while lying down was classified as a transition, specifically a lying to lying transition. To identify sit to stand, stand to sit, lying to upright and upright to lying transitions, all beginning and ending segments of lying and sitting were identified. When a postural change was detected 2 s prior to and 2 s after the beginning and ending points, respectively, transitions (of either upright to lying, lying to upright, sit to stand, or stand to sit depending on the identified postures) were classified as the active seconds for postural change. Among upright movement, sitting while fidgeting was identified by the thigh angle.

2.6 Validity. Video data were imported into Windows Movie Maker (Microsoft, Seattle, WA). Two raters, each with greater than one year of gait analysis experience, manually determined start and end times of each postural orientation and movement. The video data were considered the gold standard for all validation analysis. Video classification and accelerometer data were organized into one second windows for a second-by-second comparison. In this study, we are using the term validity to mean the "agreement between two efforts to measure the same thing with different methods" with one of those methods being the gold standard [31]. Validity of the accelerometer algorithm to properly identify different postures and movement was assessed with sensitivity and positive predictive value (PPV). Specificity was not used as the number of true negatives would depend largely on the time duration of the protocol (as more time was spent not performing each task than performing each task during the protocol) and specificity would, therefore, not provide a valuable measure in regards to accuracy in this study. Sensitivity described the percentage of an observation category which was correctly detected by the activity monitors, or the ratio of true positives to the sum of true positives and false positives. PPV provided the percentage of true positives that was identified when compared to the total number of true positives and false positives determined by the activity monitor. Misclassification error was also calculated as the percentage of disagreement between the algorithm and the video analysis for detecting all movement and static postures of standing, sitting and lying across the total protocol time [12]. There are no defined acceptable levels of sensitivity or PPV for posture and movement detection. Similar to previously published guidelines for κ values [32], sensitivity, and PPV were divided into three

levels in this study: less than 60%, between 60% and 80%, and $\geq 80\%$ [27]. Comparably, 70–80% is defined as acceptable levels for sensitivity and specificity for developmental screening tools by the American Academy of Pediatrics. In [33], a sensitivity of 71.7% and a specificity of 67.8% were deemed to be acceptable for detecting sitting postures in healthy children. In Ref. [12], a misclassification error of approximately 11% was considered as acceptable for most clinical applications. The overall accuracy of a single accelerometer or an accelerometer combination, in the present study, was determined to be acceptable at detecting a specific posture or movement if both sensitivity and PPV were greater than 60%. Acceptable accuracy was further classed as either 'moderate' or "high" with the criteria for high accuracy being that both sensitivity and PPV are $\geq 80\%$. The Bland-Altman method was utilized to compare the total time spent in upright movement as determined by both the algorithm and video observation [34].

3 Results

All twelve participants completed the protocol as prescribed. For one individual, the waist accelerometer came loose during the laying down transitions, and therefore all subsequent analyses during the protocol for this subject were not utilized for any accelerometer combinations or placements. The total time to complete the protocol averaged 359 ± 42 s. Reliability of video observation between the two raters was high for all postures and activities ($ICC(A,1) > 0.92$) except for transitions ($ICC(A,1)$ of 0.47) [27]. All further analyses were performed comparing accelerometer identification to a single rater.

3.1 Standing. Thigh-ankle and single thigh accelerometers identified standing with moderate accuracy (median sensitivities and PPVs $> 75\%$; Tables 2 and 3, and Figs. 3 and 4).

3.2 Standing/Sitting. The single waist identified standing/sitting with moderate accuracy (median sensitivity and PPV $> 71\%$; Table 2, Figs. 3 and 4). However, the single ankle demonstrated unacceptable accuracy with only 53% in median sensitivity.

3.3 Sitting. The thigh-ankle accelerometers identified sitting with moderate accuracy (median sensitivity and PPV $> 69\%$; Tables 2 and 3, Figs. 3 and 4).

3.4 Sitting/Lying. The single thigh accelerometer detected sitting/lying with high accuracy (median sensitivity and PPV $> 84\%$; Tables 2 and 3, and Figs. 3(b) and 4(b)).

3.5 Lying. The single waist accelerometer identified lying with high accuracy (median sensitivity and PPV $> 97\%$), while thigh-ankle and single ankle accelerometers demonstrated

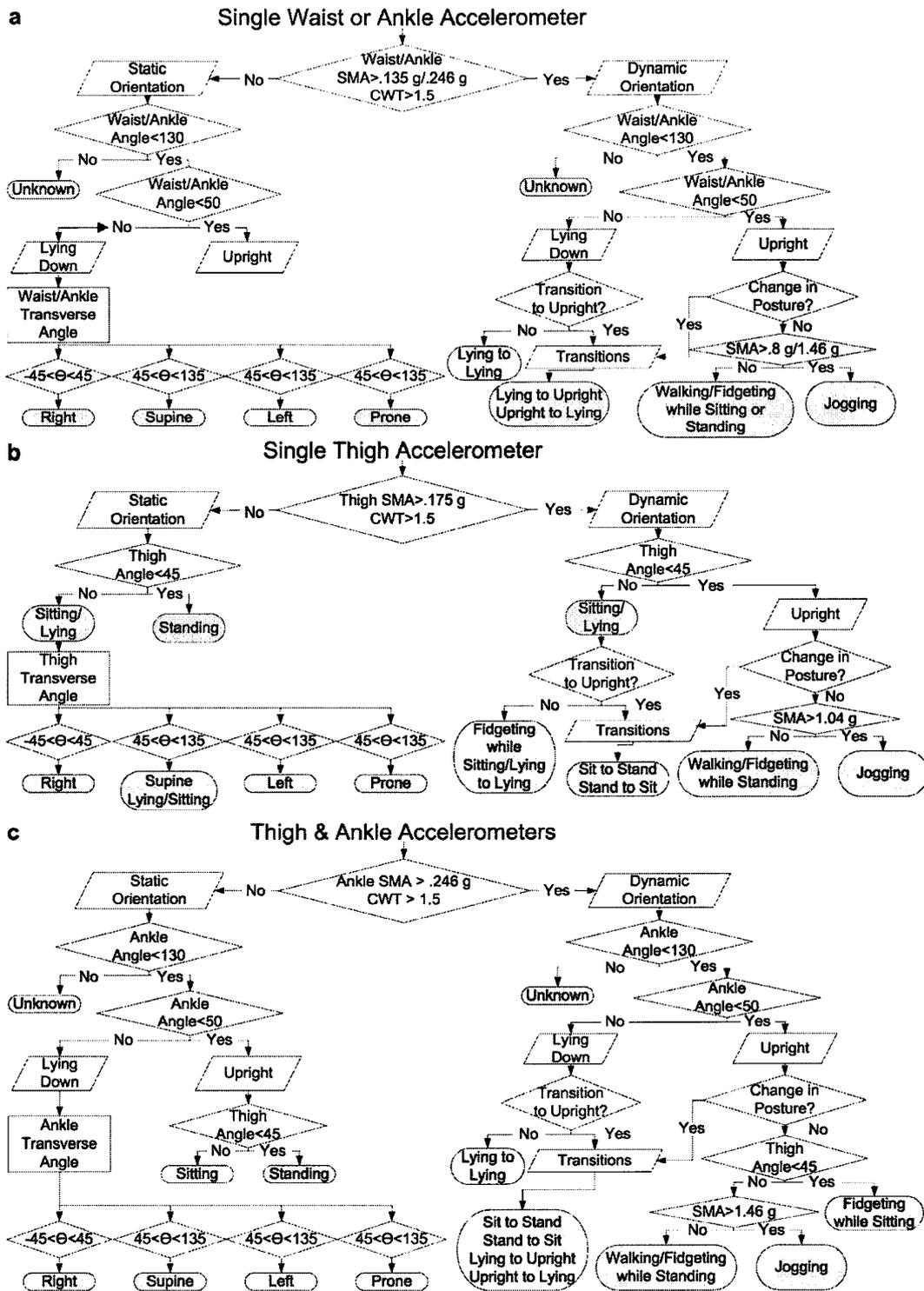


Fig. 2 Decision algorithm for the possible posture and movement classifications determined from the accelerometer data when using (a) single waist or ankle, (b) a single thigh, and (c) thigh and ankle accelerometers. SMA is signal magnitude area and CWT is continuous wavelet transform

moderate accuracy (median sensitivities and PPVs > 67%; Tables 2 and 3, and Figs. 3 and 4).

3.6 Transitions. Transitions between sitting and standing, and lying to lying were identified for the thigh-ankle and single

thigh accelerometers with moderate accuracy (sensitivities and PPVs > 77%; Tables 2 and 3, and Figs. 3 and 4). Transitions were detected with unacceptable accuracy with median sensitivity < 47% for single waist and single ankle accelerometers as only transitions between upright and lying, and lying to lying

Table 2 Median sensitivity and PPV and overall misclassification error (SD) for different monitor locations. Bold indicates highest value in each row (lowest for misclassification error), red indicates poor accuracy ($\leq 60\%$ [32]). The Waist and Thigh column data is taken from [27] for comparison

Sensitivity (%)	Waist and thigh		Thigh and ankle		
	Waist	Thigh	Waist	Thigh	Ankle
Standing	86	75	79 ^a	75	53 ^a
Sitting	97	43		98 ^b	
Lying	98	98	98		98
Walking/Fidgeting	87	94	91	94	95
Jogging	97	99	97	99	93
Transitions	87	81	46	81	43
PPV (%)					
Standing	75	87	71 ^a	87	71 ^a
Sitting	69	54		84 ^b	
Lying	97	69	97		67
Walking/Fidgeting	95	93	76	93	79
Jogging	100	99	100	99	98
Transitions	71	77	86 ^a	77 ^b	82 ^a
Misclassification Error (%)	11(2)	17(3) ^c	12(3) ^a	10(2) ^b	16(3) ^a

^aStanding cannot be separated from sitting.

^bLying cannot be separated from sitting.

^cTransitions between sitting with legs straight cannot be separated from lying.

transitions could be detected, not sit to stand or stand to sit. Sensitivity values were higher for the single thigh accelerometer as only sit to lie and lie to sit transitions could not be detected. Sit to lie and lie to sit transitions also could not be detected using the thigh-ankle accelerometers as only transitions between sitting on a bed with legs straight and lying down were investigated.

3.7 Walking/Fidgeting. Among dynamic orientations, walking/fidgeting was identified with high accuracy (median sensitivities and PPVs $> 87\%$) for the thigh-ankle and single thigh accelerometers (Tables 2 and 3, and Figs. 3 and 4). Single waist and ankle accelerometers demonstrated moderate accuracy (median sensitivities and PPVs $> 91\%$ and 76% , respectively).

3.8 Jogging. Jogging was identified with high accuracy (median sensitivities and PPVs $> 93\%$) for all combinations and placements tested (Tables 2 and 3, and Figs. 3 and 4).

The amount of time spent moving while upright demonstrated good agreement, when utilizing the Bland-Altman method to compare the accelerometer combinations and placements to video observation (Fig. 5). The single thigh accelerometer and thigh-ankle accelerometers showed approximately 1% of mean error in identifying how many seconds dynamic movement occurred across all subjects (Figs. 5(b) and 5(d)) while the single waist accelerometer showed 12% (Fig. 5(a)). The ankle showed the worst agreement with 17% (Fig. 5(c)). Overall misclassification error between movement and static postures of standing, sitting and lying were less than 17% in all cases (Table 2).

4 Discussion

The aim of this study was to test and compare movement and posture classification schemes using different accelerometer combinations and placements. Reducing the number of accelerometers required for postural and movement assessments in free-living environments and care settings is of high importance for patient compliance [5,6]. Requesting the user to don too many devices can be cumbersome and lead to overly complicated wear instructions [5]. In addition, patients may find some accelerometer placements to be uncomfortable which could further hinder patient compliance. The waist is often the preferred location as

Table 3 Static orientation and movement identification accuracy levels based on sensitivity and PPV for varying accelerometer locations. White: unacceptable, light grey: moderate, dark grey: high.

Accuracy:	Waist-thigh	Thigh-ankle	Waist	Thigh	Ankle
Standing			A		A
Sitting				B	
Lying					
Walking/Fidgeting					
Jogging					
Transitions		C	A	B	A

Note: A:A standing cannot be separated from sitting; B: lying cannot be separated from sitting; and C: transitions between sitting with legs straight cannot be separated from lying.

accelerometers can easily be attached to belts. However, for subjects who spend most of their time in bed or do not wear a belt or trousers, the waist placement may be uncomfortable [5]. Furthermore, missing acceleration data due to failed devices and subject compliance issues often cause problems with data analysis [35]. Therefore, reducing the number of accelerometers required for analysis and using algorithms which are robust to a variety of accelerometer locations may increase patient compliance and also provide alternative analysis options. It is important to note that while it is important for patient compliance that the number of accelerometers is kept low, redundant accelerometers should be used whenever possible in case of device failure or corrupt data.

Misclassifications occurred with all accelerometer combinations and placements to some degree.

4.1 Standing. When the single thigh accelerometer or the thigh-ankle accelerometers were used, false negatives were caused by misclassification of standing as walking/fidgeting when standing still occurs between activity segments of fidgeting while standing (Table 2, and Figs. 3(b) and 3(d)).

4.2 Standing/Sitting. When the single ankle accelerometer was used, a large number of false negatives (Table 2, Fig. 3(c)) resulted from subjects sitting with legs straight (i.e., on the floor or on a bed). When the single ankle accelerometer was used, false positives were due to parts of sit to stand and stand to sit transitions being misclassified as static sitting/standing when the ankle acceleration was too low to be detected as movement. When the single waist accelerometer was used, false positives were due to fidgeting of the feet while standing and sitting being misclassified as static standing/sitting when there was very little waist movement. These findings are consistent with previous studies, showing that the waist location is optimal for detecting whole body movement, while the ankle or thigh are optimal for detecting limb movement [8].

4.3 Sitting. When the thigh-ankle accelerometers were used, a large number of false negatives (Table 2, Fig. 3(d)) resulted from subjects sitting with legs straight (i.e., on the floor or on a bed). When the thigh-ankle accelerometers were used, false positives were caused by the misclassification of sitting while fidgeting as static sitting (Table 2, Fig. 4).

4.4 Sitting/Lying. When the thigh accelerometer was used, false positives (Table 2, Fig. 4(b)) were due to the start and end of lying transitions being misclassified as static sitting/lying.

4.5 Lying. When the single ankle accelerometer and the thigh-ankle accelerometers were used, a large number of false positives (Table 2, Figs. 4(c) and 4(d)) resulted from subjects sitting with legs straight (i.e., on the floor or on a bed).

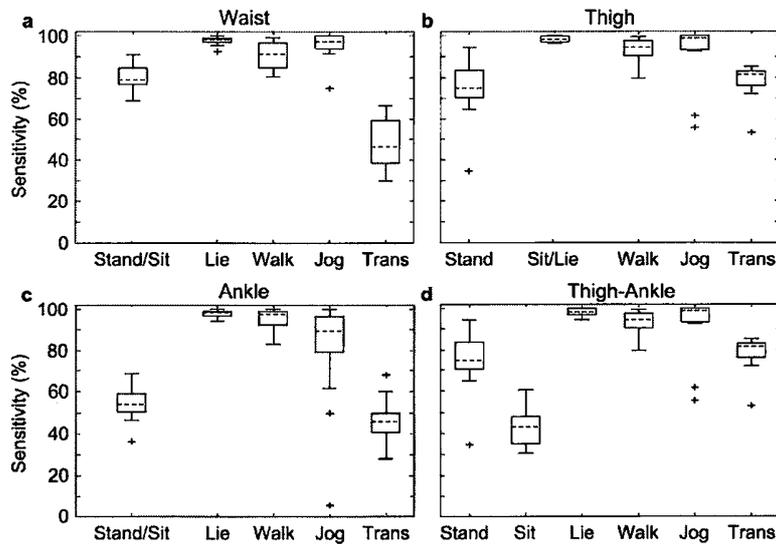


Fig. 3 Sensitivity when identifying static orientations and dynamic movements compared to video identification using (a) a waist accelerometer, (b) a thigh accelerometer, (c) an ankle accelerometer, and (d) the thigh-ankle. The central line (dashed) represents the median, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to ± 1.5 of the Interquartile range. Outliers beyond this range are labeled as +. Trans: Transitions.

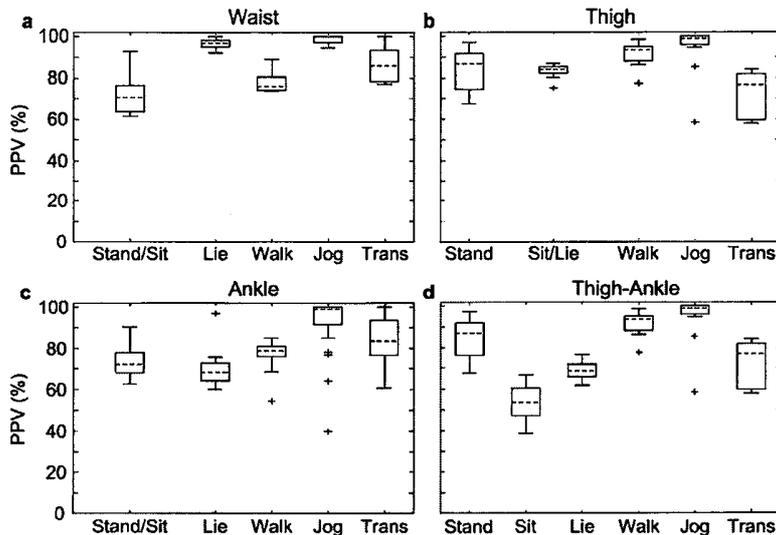


Fig. 4 Positive predictive value (PPV) when identifying static orientations and dynamic movements compared to video identification using (a) a waist accelerometer, (b) a thigh accelerometer, (c) an ankle accelerometer, and (d) thigh and ankle accelerometers. The central line (dashed) represents the median, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to ± 1.5 of the Interquartile range. Outliers beyond this range are labeled as +. For the PPV of jogging in (a), the median value and the 75th percentile are equal to 100%.

4.6 Transitions. A thigh accelerometer was needed for accurate sit to stand transition detection, and a thigh accelerometer in combination with a waist accelerometer was needed for accurate postural detection, consistent with previous studies [2,14,36]. When the single waist and single ankle accelerometers were used, false negatives occurred mostly due to transitions between sitting and standing being misclassified as walking/fidgeting, as sitting could not be separated from standing.

In this study, the thigh-ankle accelerometers were found to detect postures less accurately than the waist-thigh accelerometers in Ref. [27], however, the results were still comparable to those from other studies involving two accelerometer locations [12] and could still provide beneficial information in the event of waist accelerometer failure or if it is not feasible for a patient to wear a waist accelerometer. While some studies have investigated posture identification using only one accelerometer on the waist

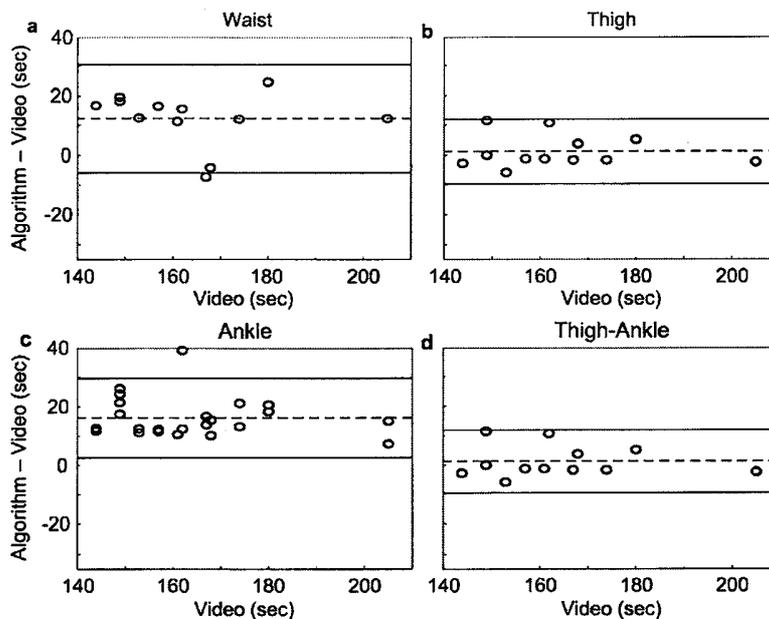


Fig. 5 Bland-Altman plots demonstrating error in identifying walking/fidgeting and jogging activities when using accelerometer compared to video identification for (a) a waist accelerometer, (b) a thigh accelerometer, (c) an ankle accelerometer, and (d) thigh and ankle accelerometers. The dashed line represents the mean, while the solid lines represent the repeatability coefficients (± 1.96 SD). ICC(A,1) values are also presented.

[15,17] or lower back [16], the protocols used to test the algorithms validities did not include fidgeting of the feet during standing or sitting postures which could possibly reduce the accuracy. Furthermore, difficulties in differentiating between standing and sitting using an accelerometer located on the waist have been reported [8]. Studies involving ActivPal placed on the thigh report combined results for sitting and lying [14,37]. In this study, the single waist accelerometer identified upright and lying postures with greater accuracy than the single ankle accelerometer.

4.7 Walking/Fidgeting. In this study, the thigh accelerometer identified walking/fidgeting with the most accuracy for single accelerometer use, while the waist accelerometer produced the least accuracy due to missed fidgeting steps. Another study reported that the ankle accelerometer demonstrated the most accurate results for walking detection with single accelerometer use between waist, thigh, and ankle location [25]. However, in this study, as sitting orientations were included in the protocol, and sitting and standing could not be separated using single waist and single ankle accelerometers, false positives occurred when fidgeting of the feet while sitting was misclassified by the algorithm as walking.

4.8 Jogging. The thigh accelerometer also identified jogging with the most accuracy for single accelerometer use, consistent with Ref. [5]. Median sensitivities and PPVs for jogging were slightly lower at 93% and 98% for the single ankle accelerometer than the other combinations and placements due to the correlation of increasing amplitude variation with increasing movement resulting in some jogging seconds being misclassified as walking and vice versa. However, despite some accelerometer locations producing more accurate results than others, all tested accelerometer combinations and placements in this study detected walking/fidgeting with moderate to high accuracy (median sensitivities and PPVs from 76% to 95%) and jogging with high accuracy (median sensitivities and PPVs from 93% to 100%; (Table 3)) which

were comparable to other studies [12,16]. While both thigh-ankle and waist-thigh accelerometers produced results of high accuracy for walking and jogging detection, the thigh-ankle accelerometers had higher sensitivity values than the waist-thigh accelerometers and only slightly lower PPVs (Table 2) consistent with a previous study on level walking, stair ascent, and descent detection [25]. The single thigh accelerometer and thigh-ankle accelerometers identified upright movement with the most agreement using Bland-Altman (Fig. 5). The misclassification errors for detecting postures and movement using the waist-thigh, single waist, and single thigh accelerometers were similar to Ref. [12] which reported a misclassification error of 11% and involved a much simpler protocol with no fidgeting of the feet or jogging. The higher misclassification errors for the single ankle and thigh-ankle accelerometers were due to errors in identifying between upright and lying postures. The single thigh accelerometer demonstrated the lowest misclassification error for single monitor use. Without fidgeting of the feet, the misclassification errors (SD) were 4% (1%), 7% (2%), and 6% (2%), 11% (1%), and 15% (3%) for the waist-thigh, single waist, single thigh, thigh-ankle, and single ankle accelerometers, respectively.

There are a number of limitations in this study which are important to consider. The disadvantage of using only one accelerometer is that in the case of device failure or corrupt data, there is no source of redundant data that can be used instead. Movement and jogging thresholds could possibly be refined in accuracy with a higher number of subjects. It is important to note that only healthy subjects were included in this study. Further investigation would be needed before using the method examined in this study on unhealthy subjects as changes in accelerometer orientations due to body shape, skeletal deformities, and skin movement artifacts could result in posture and movement classification errors. However, the healthy subjects tested in this study had a range of body types with a BMI range of 19.9–40.1 kg/m². Furthermore, the algorithm was originally designed for use with waist and thigh accelerometers and therefore the results may be biased towards the waist-thigh accelerometers. However, while the waist-thigh

accelerometers produced the most accurate results overall, all accelerometer combinations and placements detected jogging and walking/fidgeting with sufficient accuracy. For single accelerometer use, thigh accelerometer placement demonstrated optimal results as it can most accurately identify standing postures and movement and can detect transitions from sitting/lying to standing.

5 Conclusion

The results from this study show that there is a trade-off between reducing the number of accelerometers per subject, choosing their locations and accuracy. The data suggests that researchers should carefully choose accelerometer numbers and their locations depending on the information required while considering patient preferences. For posture-related tasks, we recommend using a waist and thigh accelerometer combination. For redundancy, an extra thigh accelerometer should be added. For eddynamic tasks, we recommend using a thigh accelerometer. For redundancy, an ankle accelerometer should be added. While this study involves a simulated protocol conducted in a laboratory environment, the results suggest that the proposed analysis methods are suitable for posture and movement classification in healthy adults in a free-living environment.

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Facilities and Other Resources

Laboratories: The ***Orthopedic Biomechanics Laboratory*** occupies 7,000 square feet of space located in the Guggenheim Building. The laboratory is comprised of: 1) Material testing facility for *in vitro* analysis of bone and connective tissue mechanical properties; 2) Kinematic testing facility for *in vitro* assessment of normal and pathological motion; 3) Computational stress analysis facility; 4) Specimen preparation room; 5) Experimental machine shop for machining or modifying joint implant prototypes, experimental prostheses, internal fixation devices, and testing apparatuses; 6) Tissue culture room; and 7) Tissue analysis laboratory for basic immunohistochemistry.

The ***Motion Analysis Laboratory*** occupies 7500 square feet in the Charlton North Building and is comprised of: 1) Overground and treadmill based movement analysis facilities that provide complete kinematic and kinetic analyses of gait and other functional activities;; 2) Upper and lower extremity isometric and isokinetic strength testing laboratories with a HUMAC Norm isokinetic dynamometer, a Quantitative Muscle Assessment system, a suite of hand-held dynamometers and custom-designed upper extremity strength testing equipment that includes patient fixation apparatuses for elbow and wrist. Each is interfaced with computer-aided data retrieval, reduction, and analysis capabilities; 3) In-shoe pressure mapping and floor mounted pressure mat with Tekscan F-Scan software for use in patients with diabetic neuropathies and children with clubfoot deformity; 4) Large multimedia conference room with teleconferencing capabilities and 1 small conference room for review of and/or consultation with clinical patients, their families and physicians.

Clinical: Mayo Clinic is a vertically integrated health care provider. Close cooperation exists between clinical services of Orthopedics, Physical Medicine and Rehabilitation, Rheumatology, and Neurology, thus facilitating referral of patients for functional evaluation studies.

Computer Resources: The ***Orthopedic Biomechanics Laboratory*** has a variety of computer systems for use in collection, reduction, analysis, and visualization of data. The primary system consists of a Windows NT file server (Dell PowerEdge 6300) providing a total of 740 GB of hard disk storage. In addition, CDROM and DVDROM writing facilities are available for data archiving. 40 PC compatible computers are available for data acquisition, computer aided design, word processing, and presentation graphics. Ten of these systems have analog to digital data collection capabilities. Additional computing resources are available from the Biomedical Imaging Resource and the Microcomputer Resource Center. Hardcopy devices include: 7HP LaserJet or DeskJet printers, and 1 Xerox Phaser 6200 color printer. Additional printing capabilities are available through the Biomedical Imaging Resource. All systems are connected via high-speed Ethernet and have access to the Internet for nationwide and international networking capabilities.

Analysis capabilities include finite element analysis and modeling using ABAQUS (Abaqus, Inc.) and Patran (MSC Software). These packages provide linear and nonlinear stress analysis with capabilities for nonlinear material definition and contact force analysis. Three-dimensional image reconstruction and visualization software is performed using Analyze (Biomedical Imaging Resource, Mayo Medical Center). Data collection codes and motor control algorithms are written in LabView (National Instruments). Data analysis code is written in Matlab (MathWorks). Animation of kinematic data is performed using 3D Studio MAX (Autodesk, Inc.). VIMS (Virtual Interactive Musculoskeletal System, John Hopkins) is used for discrete element analysis of rigid bodies. In addition, several locally developed software packages provide kinematic and kinetic analysis, visualization, and joint contact modeling.

Three six-degree-of-freedom magnetic tracking devices (two Polhemus Fastraks, and one Ascension Technology Flock of Birds), one active marker optoelectric tracking device (NDI Optotrak Certus), and one passive marker video tracking device (Motion Analysis Corp.) provide for real-time kinematic and analog data acquisition. The MotionMonitor software (Innovative Sports Training, Inc) provides data collection, analysis, and animation of data from these systems.

The ***Motion Analysis Laboratory*** has a variety of state of the art computer systems for use in collection, reduction, analysis, and visualization of data. There are approximately 30 computers in work areas for lab staff, physicians, fellows, and students, and an additional 15 machines dedicated to the various data collection stations within the laboratory. All are connected to the Mayo network via Mayo Research Computing Facility (RCF), a Beowulf-style Linux server cluster. RCF provides cross-platform access to file servers, databases, shared printers, the Internet, shared server-based software and other resources. Automated data backup and recovery and more than 120 terabytes of storage are also available through RCF. The Motion Analysis Laboratory is well equipped with three black and white and one color networked printers, one copy machine, three scanners, and one fax machine.

Offices: Adequate office space exists within the laboratories to meet the needs of all personnel included in this grant request.