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The Impact of Walker Style on Gait Characteristics in Non-assistive Device Dependent older Adults

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THE IMPACT OF WALKER STYLE ON GAIT CHARACTERISTICS
IN NON-ASSISTIVE DEVICE DEPENDENT OLDER ADULTS

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May 2017

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ABSTRACT

BACKGROUND AND PURPOSE: Approximately 24% of adults over the age of 65 have reported using an assistive device (AD), and this number is expected to rise in the next 25 years as the population ages. Although ADs are used to improve balance and increase independence, the impact of ADs on gait characteristics needs further exploration due to limited literature. The purpose of this study was to compare the impact of different ADs on gait speed, stride length, double limb support, and pelvic rotation in non-AD dependent, community-dwelling older adults. The results could prove useful in guiding clinical decision making when prescribing an AD to older adults.

METHODS: Twenty-eight subjects (\bar{x} =69.5, range 55-92 years old) completed the study, with six subjects being male. The BTS G-Walk, a tri-axial accelerometer, was used to measure gait characteristics during four separate conditions: walking without an AD, using a two wheeled walker (2WW), using a four wheeled walker (4WW), and using a novel device known as the Gaiter. Subjects completed three trials of each condition in random order along a 100 foot walkway. A one-way ANOVA was used to analyze data for differences in gait speed, stride length, double limb support, and pelvic rotation between conditions.

RESULTS: The results of the one-way ANOVA showed a significant difference in double limb support ($p=0.025$). No significant differences were noted in stride length ($p=0.191$), gait speed ($p = 0.092$), or pelvic rotation ($p= 0.47$). However, gait speed approached significance when any AD was used. Gait speed was slowest with 2WW and 4WW ($\bar{x}=1.15$ m/s). A post-hoc analysis revealed an increase in double limb support when subjects ambulated with a 4WW compared to no AD ($p=0.03$).

CONCLUSION: These results suggest that walker style does not significantly impact most gait characteristics in older individuals that are not dependent on an AD. The variable most impacted was double limb support, which is consistent with current literature. Increased double limb support has been shown to decrease gait speed and increase risk of falls. This study holds clinical significance in that the prescription of a walker in non-AD dependent older adults has the potential to negatively impact gait.

ACKNOWLEDGEMENTS

We would like to thank the grant writers that allowed for the purchase of the BTS G-Walk, which was instrumental in data collection. We also would like to thank Dr. MarySue Ingman and Professor Deborah Madanayake for their guidance and support throughout the entire project.

The undersigned certify that they have read, and recommend approval of the research

project entitled:

**THE IMPACT OF WALKER STYLE ON GAIT CHARACTERISTICS
IN NON-ASSISTIVE DEVICE DEPENDENT OLDER ADULTS**

Submitted by:
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in partial fulfillment of the requirements for the Doctor of Physical Therapy Program

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CHAPTER I

INTRODUCTION

Every year in the United States over 800,000 people are hospitalized as a result of falling.¹ In 2015, the cost to treat falls was estimated to be as high as \$31 billion.² Some risk factors that increase an individual's risk of falling include impaired strength, balance, medication use, range of motion limitations, environmental factors, chronic disease, and vision changes.^{3,4,5} Evidence shows that multifactorial interventions may reduce fall risk, including exercise, minimizing use of medications, environmental modifications, proper footwear, and use of assistive devices (AD).^{6,7}

Assistive devices help to increase stability by widening the base of support and by allowing individuals to use their upper extremities for assistance.^{6,8,9} In 2011, approximately 24% of adults over the age of 65 reported using an AD in the past month.¹⁰ This number is expected to rise in the next 25 years, as the number of individuals over the age of 65 is expected to double.¹⁰ Some common ADs that are used in the United States today include a single point cane, two wheeled walker (2WW), and four wheeled walker (4WW). Although ADs have been shown to improve balance and increase independence¹¹, the impact of AD use on specific gait characteristics needs further exploration.

Gait characteristics most commonly studied include gait speed, stride length, and double limb support. An individual's measure on these variables has been correlated to risk for falls.^{12,13} In particular a slower gait speed, decreased stride length, and increased time spent in double limb support have been linked to a higher

risk of falling.^{4,14,15} For this reason, it is important to consider how an individual's gait variables change when using an AD. It would be beneficial to identify which ADs lead to gait characteristics most consistent with walking without an AD. Currently there is extensive research showing how ADs alter gait characteristics in individuals with pathologies, those who are injured, and those dependent on ADs; however there is a lack of evidence about how AD usage affects independent community-dwelling older adults.

The purpose of this study was to compare the impact of different ADs on gait speed, stride length, double limb support, and pelvic rotation in non-AD dependent, community-dwelling older adults. This study examined gait characteristics when subjects used a 2WW, 4WW, and a novel device called the Gaiter. The results from this study may guide physical therapists as they consider the style of AD to prescribe to their patient. It may also help health providers to determine which AD will be least likely to alter patients normal gait while at the same time providing the necessary balance support. The study may also yield ideas for the construction of new AD which could better replicate the gait characteristics of a normal gait pattern in a pathological population.

CHAPTER II

REVIEW OF RELATED LITERATURE

Normal gait consists of a progression through a defined, sequential cycle of lower extremity movements. Gait is divided into two phases: stance phase and swing phase. The majority of the gait cycle occurs in stance phase, where the reference leg is supporting the individual's body weight and allowing for translation of the body over the reference limb.¹⁶ Stance phase consists of five subphases: initial contact, loading response, midstance, terminal stance, and pre-swing. Initial contact begins the gait cycle with the foot of the reference leg contacting the ground. After initial contact, the individual's body weight is transferred onto the reference limb in loading response. The body is then translated over the reference limb in midstance, and the body continues to progress ahead of the reference limb in terminal stance. The final phase of stance phase is pre-swing, where body weight is transferred from the reference limb to the contralateral limb in preparation for swing phase. Swing phase occurs when the reference limb is no longer weight-bearing, and is progressing forward to initiate another step. Swing phase consists of three subphases: initial swing, mid-swing, and terminal swing. In initial swing, the reference foot leaves the ground. The reference limb advances forward via hip flexion in mid swing. Finally, in terminal swing the reference limb extends in preparation for another initial contact.¹⁷ The correct progression of all of these phases of the gait cycle are repeated to result in a normal gait pattern.

Normal gait can also be described by various gait parameters. Gait parameters include step or stride length, step width, gait speed, pelvic rotation, double limb support, single support time, gait cadence, and displacement of center of gravity.¹⁶ The distance between successive heel strikes on opposite feet is known as the step length.¹⁶ Stride length is defined as the distance between heel strikes of the same foot.¹⁸ In normal gait, stride length should be equal for right and left lower extremities. Gait speed is the speed at which an individual walks, and is typically reported in meters per second. Movement of the pelvis is another aspect of gait. A vertical shift in the pelvis in the frontal plane occurs during gait to decrease vertical excursion of the center of gravity.¹⁶ Pelvic rotation about the transverse plane is present during both swing and stance phases. Pelvic rotation lessens the angle of the femur with the floor, therefore decreasing the amplitude of displacement of the body's center of gravity. On average, there is a total of eight degrees of pelvic rotation during the gait cycle.¹⁶ Double limb support is the percentage of the gait cycle that an individual spends with both lower extremities on the ground, which occurs during the loading response and pre-swing phases of gait.¹⁹ Double limb support can also be reported in seconds. Many of these gait parameters have been researched in detail in order to determine parameter changes among different populations and normal values for different age groups and genders have been reported by researchers. In this literature review and study we will be focusing on differences in stride length, gait speed, pelvic rotation, and double limb support.

Normal Gait Values and Age Related Changes

Gait Speed

Normative values for many gait characteristics have been established in previous literature. A large meta-analysis by Bohannon and Andrews provided normative values for gait speed, with evidence from 41 studies that measured normal gait speed in healthy males and females between 20 and 99 years of age, and can be used as a reference guide.²⁰ Another large study completed by researchers at the Mayo Clinic determined that there is little difference in gait speed between genders when corrected for height.¹⁸ According to a study performed by Rancho Los Amigos Rehabilitation Center, normal gait speed values for individuals aged 20-69 are 1.32 m/s for females and 1.37 m/s for males.¹⁷ Normal gait speed values for individuals over the age of 70 were found to be 1.12 m/s for females and 1.28m/s for males.¹⁷

Other studies have shown similar trends with gait speed decreasing as individuals age.^{18, 21} For instance, one study found that subjects aged 70-79 had faster gait speed than those 80 and older.¹⁸ Another study by Jerome et al. found that 23% of healthy older adult subjects aged 60 to 89 had a perceivable decline in gait speed over an average of three years of follow-up.²² Additionally, a study by Samson et al. measured gait speed in healthy subjects aged 19-90, and found that gait speed significantly declines with age in both females and males.²¹ According to the available literature, as an individual ages his or her gait speed likely will decline.

Stride Length

Studies have also established normative values for stride length across the lifespan. One large study found that females aged 20-69 had an average stride length of 1.32 m, compared to a stride length of 1.48 m for males in the same age group.¹⁷ Females and males aged 70 and above were found to have stride lengths of 1.12 m and 1.34 m, respectively.¹⁷

Other studies have also found that stride length can shorten with age. For example, a study by Hollman determined that adults aged 70-79 had longer stride length when compared to healthy individuals 80 years of age and older.¹⁸ These researchers concluded that even individuals in good health may experience some decline in gait characteristics with age.¹⁸ A separate study by Judge et al. determined that healthy older subjects with an average age of 79 years old had a 10% shorter step length than healthy younger subjects with an average age of 29.²³ Another study found that stride length significantly declines with age in both males and females.²¹

Double Limb Support

Double limb support can also change with age, with the percentage of the gait cycle spent in double limb support typically increasing. One study found that males aged 70-74 spent an average of 26.3% of the gait cycle in double limb support while males aged 80-84 spent 27.4% of the gait cycle in double limb support. Males over the age of 85 spent 30.3% of the gait cycle in double limb support. Females in the 70-74 age group spent 27.1% of the gait cycle in double limb support, compared to females aged 80-84 who spent 29% of the gait cycle in double limb support. Females over the age of 85 had an average of 28.7% of the gait cycle spent in double limb

support. This study concluded that men tend to have slightly longer double limb support than women and that double limb support tends to increase slightly across both genders with age.¹⁸

The increased time spent in double limb support with aging is often reflective of a decrease in gait speed.²⁴ There are many potential explanations for why gait parameters can be negatively impacted by age including declined lower extremity strength or decreased balance. Changes in these measures could lead to a fear of falling, and an individual may compensate by shortening steps and decreasing speed, which therefore could increase the time spent in double limb support.

Pelvic Rotation

Pelvic rotation has also been analyzed, though not to the same extent as other gait characteristics. The pelvis has been found to rotate approximately 4° anteriorly on the swing leg, and 4° posteriorly on the stance leg to decrease vertical displacement of the center of gravity.¹⁶ The femur moves from an internally rotated position to an externally rotated position during stance phase when the limb is in contact with the ground.²⁵ This rotation at the hip may allow for normal step length. There is currently no research available that assesses if there is a change in amount of pelvic rotation with aging.

Gait Changes and Fall Risk

Numerous studies have found that changes in gait characteristics with age have contributed to increased fall risk. Older adults who have fallen have significantly decreased gait speed and stride length compared to older adults who

have not fallen.⁴ Additionally, individuals who have fallen multiple times tend to have slower gait speed and decreased stride length.¹⁵ Another study concluded that older subjects with slow or fast gait speeds tend to have higher rates of falls than those with normal gait speeds.¹³ The same study found that a decline in gait speed of greater than 0.15 meters per second is predictive of falls.¹³

The percentage of the gait cycle spent in double limb support can also be attributed to fall risk. A double limb support time increase of 10 percent has been found to be predictive of falls.¹⁴ These studies support a link between changes in gait parameters and increased risk of falling. Often, older adults who have fallen or are at an increased fall risk will choose to utilize an AD for ambulation, and it is important to determine which device will achieve a gait pattern most consistent with normal values.

Purpose of Assistive Devices

Assistive device usage is extremely common in the United States, with 24% of older adults reporting AD use in the past month.¹⁰ Tools such as walkers and canes are often used in the treatment of balance deficits and gait abnormalities because ADs can increase an individual's base of support to improve stability.^{6,8,9} Assistive devices have also been prescribed to help individuals maintain independence.^{6,8} This is of prime importance as 30-40% of community-dwelling adults over age 65 fall each year, and the rates are even higher among older adults residing in nursing homes.²⁶ Assistive devices have been shown to be useful in improving mobility and balance in many populations, from those with general

weakness or joint pain, to individuals with Parkinson's disease.^{4,6,9,27,28} Devices can also be used in re-learning how to walk after surgery or trauma.⁶ Assistive device usage has been shown to reduce fear of falling and possibly improve the patient's confidence level, which might result in higher activity levels.²⁹⁻³¹

There are a variety of different ADs available to help improve gait function in older adults. Assistive devices include walkers, walking poles, crutches, and canes. Many different types of walkers are commercially available, with 2WW and 4WW being the most common styles of walkers utilized. A 2WW has two wheels positioned on the front of the walker and two flat pieces on the back to allow for a balance between mobility and stability. A 4WW contains four wheels, which allows for increased ease of movement and manipulation. This type of walker is typically prescribed for individuals who have less concern about stability. A 4WW can also include the option of a fold-down seat and front basket. A cane can be utilized in individuals with unilateral lower extremity weakness to help support body weight during stance phase on the weak limb. A cane can also help to provide increased stability to those with poor balance.³¹ The type of AD recommended depends on an individual's specific gait needs. When prescribing an AD, a physical therapist must consider unique factors to the patient, including strength, balance, previous use of AD, affordability, home environment, and specific movement precautions.

There are relatively few studies available that look specifically at gait parameters when using a 2WW or a 4WW in a healthy, non-AD dependent population. There are, however, more studies that examine how the use of different

types of ADs impact gait characteristics in diseased, injured, or AD dependent populations. The following sections will elaborate on the current available research regarding changes in gait characteristics when using 2WW and 4WW in different types of subject populations.

2WW and Gait speed

Kegelmeyer conducted a study examining how 2WW usage affects gait speed in a subject population with Parkinson's disease.²⁷ The study used a case series design on 27 subjects with an average age of 69.7 years old who were diagnosed with Parkinson's disease. The study measured gait characteristics with a GaitRite including stride length, velocity, percent swing time, and double limb support in subjects using various AD compared to no AD. Results showed the 2WW significantly slowed gait speed when compared to no AD in those with Parkinson's disease.²⁷

Another prospective cohort study by Liu et al. consisted of 18 current 2WW users and 15 potential walker users that had either fallen or been hospitalized for non-surgical pathologies in the three months prior to the study.⁴ The potential walker users had also been considering using an AD in the past few months. The researchers used a GaitRite to examine differences in gait parameters. This study found that gait speed decreased from 1.02 meters per second to 0.93 meters per second when using a 2WW compared to ambulating with no AD. The researchers also found that the group that had been long-term users of a 2WW had a decreased gait speed when compared to the potential walker group when walking with a 2WW. The authors concluded that

increased time using a walker may cause an even further decline in gait speed and stride length.⁴

4WW and Gait speed

Lucki conducted a study including 28 subjects that were consecutively admitted to a hospital.²⁹ Ten of the subjects were using a walker for at least three months prior to data collection, nine were instructed to use a 4WW for three days prior to data collection, and nine used a 4WW for data collection only. Subjects completed the Timed Up and Go (TUG) and 6 Meter Walk Test for gait speed while using a 4WW as well as without an AD. There was a significant increase in gait speed when using the 4WW when compared to no AD for all three groups in the study. Timed Up and Go scores while using the 4WW were significantly worse in the group that used the 4WW for data collection only. This is likely due to the TUG requiring a sharp turn and individuals not being confident with turning when using a walker. No significant differences were found in TUG times when comparing the use of the 4WW to no AD in the 4WW user group or the group who had been using the 4WW for the past three days. The authors hypothesized that the increased gait speed when using a 4WW was due to an increased confidence and feeling of safety and security.²⁹

A retrospective cross-sectional study examined gait characteristics and sought to determine the differences in gait parameters when using or not using an AD.³² The study included community-dwelling adults over the age of 60 who used a crutch, cane, or 4WW for mobility. This study found there were significant increases in gait

speed when using a 4WW when compared to walking without an AD in a population that currently was utilizing an AD.³²

Another study by Schwenk et al. examined how the use of a 4WW impacted gait and mobility in a geriatric population with multiple medical diagnoses in an inpatient rehabilitation facility.¹¹ When comparing the use of the 4WW to no AD in the subjects, there were large differences seen in gait speed. The average gait speed with a 4WW was 0.83 m/s, while the average gait speed without an AD was 0.63 m/s.¹¹ It is important to note that the subjects were using a walker before the initiation of the study. Of the subjects included, 77% of the subjects had a moderate-severe functional impairment based on the Barthel Index and 16% of the participants were unable to perform the baseline tests without a 4WW due to fear of falling.

Cetin et al collected data to determine the energy cost of gait and compare the use of a 4WW to a pick-up walker, which is a walker with four legs and no wheels.³³ Subjects included 30 patients over 65 years old that were admitted to a geriatric care facility. This study found significant differences in gait speed and TUG scores in subjects using a pick-up walker and a 4WW. There was a significant decrease in TUG times and a significant increase in gait speed when using the 4WW as compared to the pick-up walker.³³ The four wheels present on a 4WW may result in a 4WW being easier to propel than a pick up walker, as a pick-up walker has no wheels and must be lifted by the subject to advance. The TUG also requires the individual to complete a 180 degree turn, and a 4WW may be easier to maneuver while turning.

Bryant et al analyzed gait speed in 10 subjects with Parkinson's disease who were not using an AD at baseline.³⁴ Subjects' gait was assessed when using a 4WW, a single point cane, and no AD. Results showed gait speed was significantly decreased with the use of the 4WW or a single point cane when compared to gait without an AD.³⁴ This may be due to the research study gathering data immediately when they began using the AD and not providing any instruction on how to use them.

It is important to acknowledge that these studies have included populations with a medical diagnosis that can influence gait quality or who have previously been utilizing an AD for mobility purposes. Therefore, the findings of these studies may not accurately reflect the impact of AD usage on gait characteristics in healthy, non-AD dependent adults using an AD for the first time.

2WW and Stride length

Stride length is another gait parameter that has been researched in multiple studies. Kegelmeyer et al examined the effects of a 2WW on gait characteristics in a population with Parkinson's disease.²⁷ Subjects showed significant decreases in stride length when using the 2WW when compared to no AD, with average stride length measuring 0.93 meters when using a 2WW and 1.11 meters when not using an AD.²⁷ This study only included subjects with Parkinson's disease, and this pathology can cause neurological changes that influence both quality of movement and motor learning. It is unknown how much this diagnosis actually affected the results that this study found.

The study by Liu that examined the effects of walker use in current 2WW users and potential 2WW users also found significant decreases in stride length for all subjects when using a 2WW.⁴ The researchers in this study determined that the current walker user group also showed a decrease in stride length compared to the potential walker users.⁴ Both of the studies described in this section found that use of a 2WW actually decreased stride length in the subjects tested.

4WW and Stride length

Most studies that compared the use of a 4WW to no AD generally found an increase in stride length amongst subjects. Härdi et al. studied community-dwelling adults over the age of 60 who used a crutch, cane, or 4WW for mobility.³² The researchers found significant differences in stride length when using a walker versus no AD. Those using a 4WW were found to have greater stride length when walking versus those not using a walking aid.³²

Schwenk et al. had similar findings. These researchers examined how the use of a 4WW impacts gait and mobility in a geriatric population with multiple medical diagnoses in an inpatient rehabilitation facility. Large and significant differences in stride length were seen when comparing walking with a 4WW to walking without an AD. When walking with a 4WW, subjects demonstrated an average stride length of 0.91 meters and when walking without an AD, 0.69 meters.¹¹ These studies were completed on subjects that were already using an AD and a 4WW may provide an individual with an increased feeling of stability, therefore resulting in an increased stride length.

One study reported a decrease in stride length with use of a 4WW.³⁴ This study examined subjects with Parkinson's disease and showed a significant decrease in stride length when using a 4WW, when compared to walking with use of a single point cane or without an AD.³⁴ The subjects included in this study were not consistent AD users and did not receive education on how to properly use the 4WW, and these aspects may have attributed to the results found.

2WW and Double Limb Support

Another characteristic of gait that has been studied is how various AD affect double limb support time during gait, although this gait characteristic has not been studied as in depth as gait speed and stride length. The study by Kegelmeyer et al. investigated the effects on double limb support when a subject was using a 2WW as compared to using no AD in patients with Parkinson's disease.²⁷ This study found slight differences across the two groups, with a double limb support of 26.3% of the gait cycle when using a walker and a double limb support of 33.6% when walking without an AD. The differences in double limb support time were not found to be statistically significant in this study.²⁷ No other studies examining the effects of double limb support time with a 2WW were found.

4WW and Double Limb Support

There are more published studies that analyze changes in double limb support when using a 4WW. One study conducted by Hårdi et al measured double limb support time while using a 4WW and when not using an AD in community dwelling older adults that were using some type of AD for mobility.³² This study determined

that there were no differences seen in double limb support time when comparing walking with a 4WW versus no walker. It did, however, show that double limb support time was significantly increased in the group that used the 4WW regularly when compared to the matched controls that did not use any AD.³²

Another study investigated how the use of a 4WW affects the amount of time spent in double limb support for subjects with Parkinson's disease specifically. These researchers found that double limb support time was very similar when using a 4WW and when walking without use of an AD, with double limb support times measured at 26.3% and 26.6% of the gait cycle, respectively.²⁷ Another study of subjects with Parkinson's disease that compared the use of a cane, a 4WW, and no AD also determined that there were no significant differences in double limb support phase when comparing the three groups.³⁴

A study by Liu examined how the use of a 4WW affected gait characteristics in potential AD users and current AD users.⁴ The researchers found significant differences in double limb support time between the groups. When a potential AD user used an AD compared to no AD, they showed a significant increase in double limb support time. However, the current AD users demonstrated a significantly longer time spent in double limb support in comparison to the potential users when using a walker.⁴ This research study raises the question as to whether the long-term use of an AD results in increased double limb support time.

As previously stated, an increase in double limb support is linked to an increased risk of falls. It is important for a physical therapist to be aware of the

impact that longer double limb support time can have on an individual, and take into account changes in double limb support time with various ADs.

Other ADs

Other studies have been completed to examine the effects of assistive devices that are similar to traditional walkers. In a study of 21 patients with COPD, subjects completed a 6 Minute Walk Test with no AD, a 4WW, and a new ambulation aid called the modern draisine.³⁵ The modern draisine is similar to a bicycle but with smaller wheels and no pedals. Results of this study showed a significantly longer 6 Minute Walk Test distance with the use of the modern draisine as compared to the 4WW. There was also a significant difference in stride length, with a greater stride length seen when using the modern draisine than with the 4WW.³⁵

Another study consisting of 10 subjects compared gait characteristics when using a Merry walker, a novel device called a WalkAbout, a 4WW, and no AD.³⁶ A Merry walker is similar to a 4WW, but the user is completely surrounded by the frame and has a seat inside the frame to allow the user to sit when needed. The WalkAbout is similar to the Merry Walker, as the user is completely surrounded by the frame. The frame has one side that opens to allow the user in and out. The device also straps the user in so they can sit as needed. Significant decreases were seen in gait speed and stride length when using the Merry walker as compared to no AD. When comparing the WalkAbout and 4WW to no AD, there were no significant differences seen in gait speed or stride length.³⁶

Though the research is limited, various studies have shown in general that the use of a 2WW among different populations result in a decrease in gait speed and stride length in comparison to no AD. Conversely, the use of a 4WW supports increases in gait speed and stride length when comparing the use of a 4WW to no AD, specifically in subjects that were already using an AD. Research on double limb support time when using a 2WW or a 4WW is inconsistent, but the majority of the few studies that have included data on double limb support time have shown no significant differences. There is a lack of research regarding changes in pelvic rotation with AD.

Measurement of Gait Characteristics

It is important to be able to objectively measure gait characteristics to identify the effect that interventions have on an individual's gait pattern. One of the most common ways to measure gait characteristics is by using the GaitRite. The GaitRite has been shown to be reliable and valid.^{37,38} Multiple limitations exist for the GaitRite. It is very costly and has low portability compared to its competitors. This has lead to other companies inventing new methods of analyzing gait. One method in particular involves the use of tri-axial accelerometers. Tri-axial accelerometers can yield information about gait characteristics including gait speed, stride length, pelvic rotation, and double limb support time.

One study found that when comparing a tri-axial accelerometer system to a GaitRite there was excellent agreement for gait speed, cadence, and step length with an ICC of 0.99 for averaged data.³⁹ Another study looked at the validity of a tri-axial

accelerometer compared to stereophotogrammetry.⁴⁰ Stereophotogrammetry consists of an eight camera system with two dynamometric platforms. The researchers found no significant differences between the instruments for collected data on gait speed, stride length, stride duration, and cadence when the accelerometer was placed over the 4th and 5th lumbar vertebrae. However, this study did find significant differences for double limb support duration.⁴⁰ The results also supported previous literature that the placement of the accelerometer device over the 5th lumbar vertebrae is the most accurate placement for a tri-axial accelerometer to measure gait speed.⁴¹ In a study by Park, the BTS G-Walk, which is a tri-axial accelerometer, was shown to be significantly and highly correlated with a foot pressure sensor system, the FPS GaitRite, for gait speed, cadence, stride length, and stance time.⁴²

The company that developed the BTS G-Walk, BTS Bioengineering, tested the BTS G-Walk against its own gold standard, the BTS GAITLAB. The BTS GAITLAB consists of optoelectronic cameras, tri-axial force platforms, and surface EMG systems. The algorithm used with the G-Walk was compared to the GAITLAB with 30 adults between the ages of 25-50. The recorded data on the same trials and found a deviation between the two methods of 2.28%. The largest observed deviation between the two methods was 2.82% for the double limb support phase.⁴³ Overall there is significant agreement in the literature for the ability of a tri-axial accelerometer to accurately measure spatiotemporal parameters of gait. The current study utilized the BTS G-Walk.

Purpose

There is very little information available in the literature that describes how various assistive devices alter gait characteristics in a healthy population of adults over the age of 55. It is important to gain understanding of how ADs can impact gait characteristics in non-AD dependent older adults, as this population occasionally obtains walkers for use while traveling or, if the model features a seat, a convenient place to sit. Gait speed, stride length, pelvic rotation, and double limb support time in non-AD dependent adults were evaluated in this study in four separate conditions: ambulating independently, with a 2WW, with a 4WW, and with a novel assistive device called the Gaiter. The Gaiter is an AD that features four wheels and two handles that are able to rotate anterior and posterior and is pictured in Appendix E. The Gaiter may offer a wider base of support than traditional walkers. It has been proposed that this device could increase pelvic rotation and improve posture, however there is no evidence to support these claims. This study also sought to determine how the Gaiter compared to the other assistive devices that are commercially available and commonly prescribed by physical therapists. The null hypothesis for this project was that ambulating with an AD would not significantly impact gait characteristics compared to walking without an AD in a non-AD dependent population. However, based on cited literature on pathological patients and clinical expertise, it is plausible that ambulation with an AD may result in a decline in gait characteristics except for pelvic rotation as there was no literature found to base a hypothesis on.

CHAPTER III

METHODOLOGY

Recruitment

After acceptance from the Institutional Review Board at St. Catherine University, the research team began recruiting subjects via emailed flyers. The flyers contained brief information about the nature of the study and were emailed to St. Catherine University faculty and staff and the Doctor of Physical Therapy Senior Mentors. Interested individuals were encouraged to contact the researcher (DM) via phone. Upon calling, potential subjects were then given more information about the purpose of the study and pre-screened for inclusion and exclusion criteria. The inclusion criteria was: independent ambulation, non-assistive device dependent, aged 55 and older, and community-dwelling. The exclusion criteria was: use of a gait assistive device within the past 12 months, orthopedic surgery in lower extremity in last 12 months, observable presence of gait abnormality, and presence of pacemaker or other electronic implant. If all criteria were met, an appointment was made for data collection and a consent form was emailed to subjects for their review.

Subjects

Thirty-one community dwelling, older adults participated in the study. Only 28 of the subjects' data was included in this study, with three of the subjects data discarded due to gait abnormalities or insufficient data. Of the 28 subjects, six

were males and 22 were females, with an average age of 69.5 ± 9.71 and range of 55-92 years. The average BMI of the subjects was 26.1 kg/m^2 and ranged from 20.6 to 33.1.

Data Acquisition

The BTS G-Walk device was used to measure gait characteristics including gait speed, stride length, double limb support time, and pelvic rotation. The BTS G-Walk is a tri-axial accelerometer, which is positioned at the L4-L5 junction with an adjustable elastic strap. The data was recorded and then transferred via Bluetooth to a computer nearby.

Test Procedure

On the day of data collection and prior to participation in the study, written consent was obtained and subjects were visually screened to ensure a normal gait pattern. Height, leg length, and weight were measured. The same researcher measured height and leg length for all subjects. Weight was measured via a digital floor kilogram scale.

Subjects were then instructed to view a set of three separate videos demonstrating how to use the 2WW, the 4WW, and the Gaiter. After each video, the subject was encouraged to practice ambulating with the AD shown in the video. Subjects donned a gait belt and were able to practice ambulating with each walker as long as he or she needed in order to feel comfortable with the AD. A researcher was

present at this station, and subjects were able to ask questions for clarification on walker use. After the subjects felt confident with using the AD, they were then directed to the data collection station.

Once at the data collection station, the BTS G-Walk was fastened to the patient using an adjustable strap. The BTS G-Walk was positioned over the L4/L5 spinous processes. Each subject performed three trials of each of the four walking conditions: without AD, with the 2WW, with the 4WW, and with the Gaiter. The order subjects performed each condition was randomly selected using a computerized randomization system. The testing area was located in a gymnasium, and subjects were instructed to walk 100 feet across the gymnasium. Gait was only analyzed in the middle 75 feet by the BTS G-Walk system, to ensure steady state walking. Before initiation of each trial, the patient was instructed to stand still while the BTS system calibrated. Subjects were encouraged to walk at their normal, comfortable pace. A researcher walked slightly behind each subject and the subject wore a gait belt to ensure safety, but the researcher was out of the subject's visual field to not bias gait speed. After each trial, the researcher gathering the computerized data from the BTS G-Walk made sure that the trial data was captured. If an error occurred a repeat trial was performed. Subjects were given the option to have a seated rest break between each trial due to control for fatigue. This process was repeated for three trials for each of the four conditions. After all 12 trials of data were collected, the BTS G-Walk was removed and the subjects were free to ask any questions before leaving the study area.

Data Analysis

Two trials for each condition were analyzed, due to some subjects not having three complete data sets. Data analysis was performed with the software program SPSS. To assess for significant differences, a 1-way ANOVA was completed for each variable measured: stride length, gait speed, double support time, and pelvic rotation. The p-value was set at less than or equal to 0.05. Tukey's post hoc test was utilized when a significant p-value was found.

CHAPTER IV

RESULTS

Twenty-eight non-AD dependent community dwelling older adults completed three trials of each of the four conditions. Demographic data is listed in Table 1. Multiple subjects required additional trials to obtain data for each condition due to errors with the BTS G-Walk system. No subject required a seated rest break during the session.

Gait Speed

Figure 1 shows the mean gait speed for each of the four walking conditions. The mean gait speed determined for each of the conditions were as follows: 1.27 m/s for normal walking without an AD, 1.15 m/s for the 2WW, 1.15 m/s for the 4WW, and 1.18 m/s for the Gaiter (Table 2). There were no significant differences found between conditions for gait speed, with the p-value measured at 0.092. Although it was not significant, it is important to note there was a trend towards slower gait speed with any assistive device compared to normal walking and the p-value approached significance.

Stride Length

The mean values for stride length for each condition were as follows: 1.31 m for normal walking without an AD, 1.23 m with a 2WW, 1.21 m with a 4WW, and 1.27 m with the Gaiter. Figure 2 is a graph depicting these values for each of the four walking conditions. When examining differences in stride length between conditions,

the data yielded a p-value of 0.191. The 4WW condition showed the greatest decrease in stride length compared to normal gait, however this was not statistically different.

Double Limb Support

Double limb support means were found to be 19.7% of the gait cycle when walking without an AD, 22.3% with the 2WW, 22.6% with the 4WW, and 21.9% when the Gaiter was used (Figure 3). The 1-way ANOVA for this variable showed a significant difference, with a p-value of 0.025. Post hoc examination determined that subjects spent significantly more of the gait cycle in double limb support when using the 4WW than when walking without an AD. Results for the 2WW approached significance when compared to walking without an AD (p-value of 0.061).

Pelvic Rotation

Pelvic rotation means were found to be 5.74° ambulating with no AD, 5.47° ambulating with 2WW, 4.69° with 4WW, 5.38° with a gaiter. Although there were no significant differences for pelvic rotation, pelvic rotation did decrease in all three of the walker conditions.

CHAPTER V

DISCUSSION

The findings of this study led to the rejection of the null hypothesis, as there was a significant increase in double limb support with the 4WW. Ambulation with the 2WW and the Gaiter also showed a trend towards increased double limb support. The data analysis determined that the decrease in gait speed was not statistically significant, although gait speed data did approach significance for both the 2WW and 4WW condition and likely would have been a significant finding with a larger sample size. The data also suggested a slight but insignificant trend for decreased stride length when ambulating with a walker, and findings for this gait characteristic may also have been impacted with a larger subject sample. Pelvic rotation decreased slightly with walker use, but this finding was also not statistically significant. It is interesting to note that the Gaiter was most similar to walking without an AD when examining gait speed, stride length, and double limb support, while the 2WW was most similar to normal walking for pelvic rotation.

To a certain degree, the study findings support the previous literature that measured gait characteristics with various walker styles. In regards to gait speed without an AD, the subjects included in this study had comparable gait speed to healthy subjects in the same age range²⁰, which indicates that the population used in this study ambulated similar to other healthy, older adults. The findings of this study show no significant difference in gait speed with different walker styles, however the mean values for gait speed with the 2WW, 4WW, and Gaiter were slightly lower in

comparison to normal walking. Gait speed values approached significance with a p-value of 0.092, and significance may have been achieved with a larger study sample.

Available literature on the impact of walker style on gait speed is mixed, with studies reporting both an increase and decrease in gait speed when a walker is used. Although not significant, the current study agrees with literature from a study by Kegelmeyer, which found a decrease in gait speed when a 2WW was used in a subject population with Parkinson's disease.²⁷ A study by Liu reported similar findings with overall gait speed decreasing when using a 2WW versus no AD for current walker users and adults that may potentially benefit from an AD.⁴

The current study's findings contrast with the results from a study by Lucki, which determined that there was a significant increase in gait speed when compared to no AD for current 4WW users, those that were instructed to use 4WW three days prior to data collection, and those that did not currently use a 4WW.²⁹ Schwenk also found an increase in gait speed when subjects used a 4WW versus no AD in a geriatric population residing in an inpatient rehab facility.¹¹ It is important to note the subjects in the above mentioned studies were individuals that had medical conditions in which an AD was already being used or would be beneficial.

A significant impact on stride length was not found in this study, but a slight trend for decreased stride length was noted. The vast majority of previous studies that examined stride length when using an AD found significant decreases in stride length when using a 2WW or a 4WW. These studies included subject populations with Parkinson's disease, those who were currently using a walker, or those who had fallen

in the past. The present study explicitly consisted of independent older adults that did not regularly utilize an AD, and it is possible that stride length may be more negatively impacted in populations with an underlying pathology or dependence on a walker. Two studies found that stride length significantly increased during ambulation with a 4WW in subjects who had been using an AD, and subjects in inpatient rehabilitation.^{11, 32} Due to disagreement in current literature, further investigation on the impact of AD use on stride length would be beneficial.

Previous studies on gait characteristics when using ADs found significant increases in double limb support when ADs were used, and the current study supports this literature. During ambulation without an AD, the subjects in the current study spent 19.7% of the gait cycle in double limb support, which was an aggregate of all subjects between the ages of 55 and 92. In comparison, a study performed by Hollman determined values for double limb support in adults over the age of 70 to be between 26.3% and 27.1%.¹⁸ Overall the current study shows a decreased percentage of the gait cycle spent in double limb support compared to the research by Hollman, which might be due to Hollman's study having a minimum subject age of 70.

The current study determined that there was an increase in time spent in double limb support for all walker conditions when compared to normal walking, but ambulation with the 4WW was the only condition that was statistically significant. Subjects ambulated with an average double limb support of 22.34% with the 4WW. A similar study showed that users who were currently using a 4WW spent 34.2% of the gait cycle in double limb support compared to 29.1% of matched controls who were

not currently using an AD.³² Only 12 subjects were included in this study, with an average subject age of 84 while the average subject age for the current study was 69.5. It is possible that the advanced age of subjects could have yielded an increased double limb support time, and if the current study included an older sample similar results may have been found.

Another study by Liu that examined the impact of walker use on double limb support found that potential AD users had a significant increase in double limb support when using a 4WW.⁴ This population is similar to that of the current study, as the subjects were not currently using an assistive device. However, subjects in the Liu study were considering using a walker while subjects in the current study were not. This same study also determined that a greater percentage of the gait cycle was spent in double limb support when an individual utilized a 4WW more regularly. This is important as the increased time spent in double support has been shown to be an indicator of increased fall risk.

Due to the Gaiter being a novel device that is not currently commercially available, there is no comparison to prior data that can be examined at this time. With an average double limb support percentage of 21.88%, the Gaiter was the most similar to ambulation without an AD out of the walker styles included.

The current study showed no significant differences for pelvic rotation during ambulation with any walker. The data from this study suggests that pelvic rotation is not influenced by the use of a walker, regardless of the type of walker utilized. The mean pelvic rotation without an AD was measured to be 5.74°, which is slightly less

than the typical 8° of pelvic rotation reported in previous literature.¹⁶ It is possible that the current study did not measure noticeable differences in pelvic rotation due to the use of a healthy subject sample. No previous literature was found to examine changes in pelvic rotation with walker use, and more research needs to be completed to draw more definite conclusions.

Limitations of our study

It is important to acknowledge the potential limitations of this study. The study included a small sample size, and a larger number of subjects may have increased the power of the study. Increased power could lead to additional significant findings, especially for data that approached significance. There were some technological difficulties experienced with syncing the BTS G-Walk to the laptop, which resulted in only two full trials for some of the participants. Therefore a comparison was performed on two trials instead of three trials. There was also a potential for Hawthorne bias in this study, as subjects were aware of observation by researchers during ambulation. Subjects could have altered their gait mechanics either consciously or unconsciously due to being observed, which may have skewed the data.

Physical Therapy Implications

Based on the results of this study, it can be concluded that the use of a walker in a non-AD dependent population could negatively impact gait. This is important to note because older adults may wish to obtain a walker, especially a 4WW, to provide a place to rest while walking, or as a means to carry items when traveling or

shopping. Due to the evidence available regarding increased risk of falls when gait characteristics change, it is of the utmost importance for health care providers that prescribe ADs, such as physical therapists, to take into account the potential impact that ADs can have on patients' gait characteristics. Each patient must be considered individually, as the possible negative impact on gait characteristics when using an AD may or may not outweigh the benefits of improved balance and stability with AD use.

This research contributes to the currently limited body of evidence available about changes in gait characteristics when using an AD. Based on the literature review, this study is unique in that a non-pathological, non-assistive device dependent subject sample was utilized and this study can be used as a comparison in future studies.

Opportunities for Future Research

The completion of this study presents many opportunities for future research. This study could be used as a reference for future studies measuring the impact of ADs on populations with various medical diagnoses. Video analysis in a similar study could help to determine potential changes in posture when ADs are used, as some subjects anecdotally reported noticing a change in posture when ambulating with the various walkers. A confidence scale could be utilized to determine the subjects' comfort and perceived stability with each walker style. After participation in the study, subjects often voiced their walker preference, so a more formal gathering of qualitative information about the subjects' attitudes towards the different walker styles could be beneficial. Finally, repeated measurements over time

could be used to determine if there are changes in gait characteristics when a walker is used consistently.

CHAPTER VI

CONCLUSION

The results of this study suggest that walker style has a limited impact on most gait characteristics in older individuals that are not currently dependent on an assistive device. Double limb support was significantly impacted by walker use. Changes in gait speed also approached significance when an AD was used. This study holds clinical significance in that the prescription of a walker for previously non-assistive device dependent older adults has the potential to negatively impact gait, so the risks and benefits of assistive device use should be carefully weighed.

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Table 1. Subject demographics

	Mean (range)
Age (years)	69.5 (55-92)
Height (cm)	163.8 (152-190)
Weight (kg)	69.9 (54.7-110.5)
BMI (kg/m ²)	26.1 (20.6-33.1)
Gender	6 (21.4)

Table 2. Results of gait characteristics for all conditions

	Mean	Standard Deviation	P-value
Gait speed (m/s)			0.092
Normal walking	1.27	0.21	
2WW	1.15	0.22	
4WW	1.15	0.21	
Gaiter	1.19	0.20	
Stride length (m)			0.191
Normal walking	1.31	0.19	
2WW	1.23	0.17	
4WW	1.21	0.18	
Gaiter	1.27	0.20	
Double limb support (% of gait cycle)			0.025*
Normal walking	19.69	2.56	
2WW	22.30	3.96	0.061

4WW	22.58	4.75	0.030**
Gaiter	21.88	3.82	0.161
Pelvic rotation (degrees)			0.47
Normal walking	5.74	2.81	
2WW	5.47	2.38	
4WW	4.69	2.19	
Gaiter	5.38	2.85	

*Denotes significant difference between conditions ($p < .05$)

**Denotes post-hoc significant difference compared to normal walking.

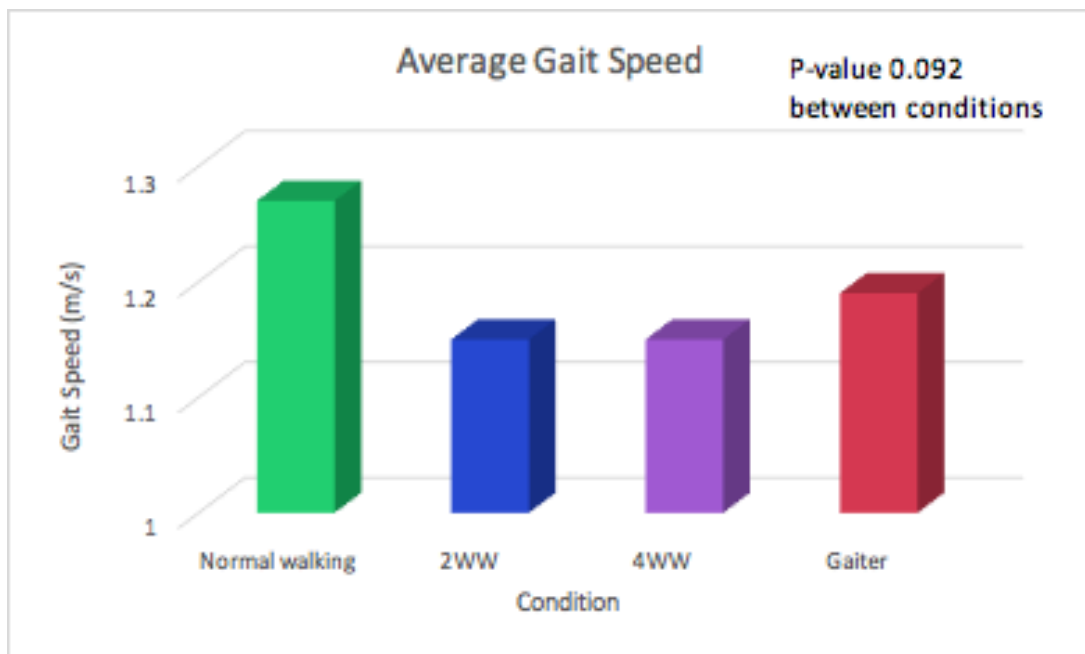


Figure 1: Gait speed for each condition

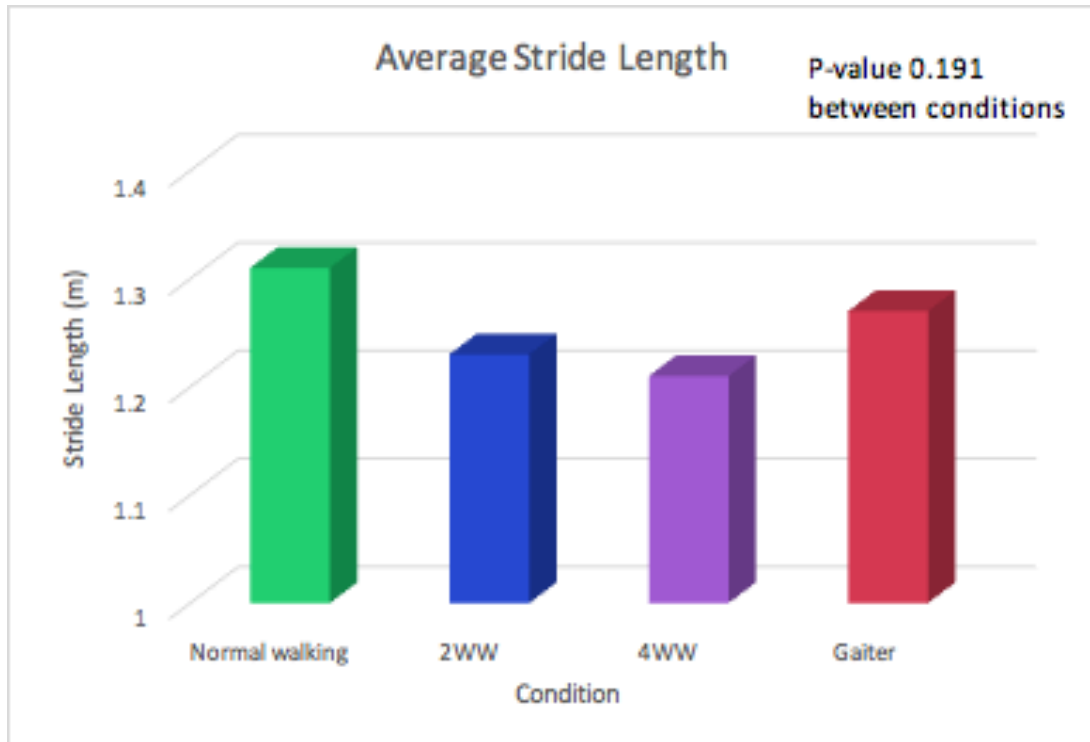


Figure 2: Stride length for each condition

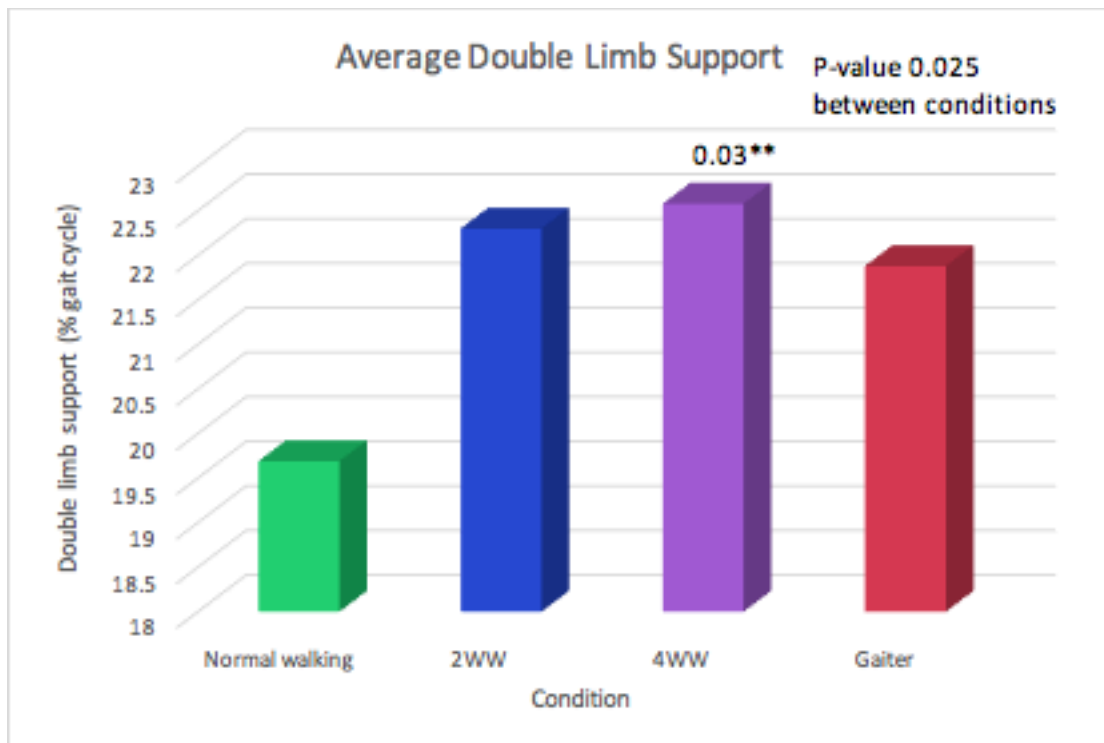


Figure 3: Double limb support for each condition

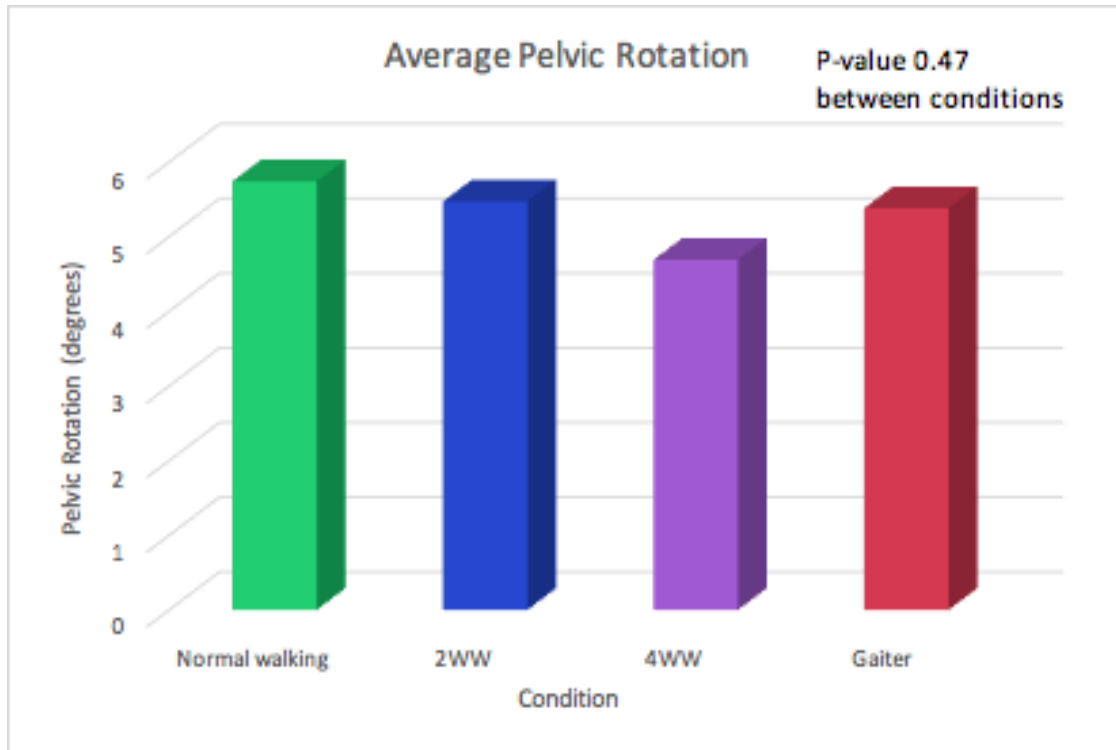


Figure 4: Pelvic rotation for each condition

Appendix A IRB Approval

To: Deborah Madanayake
From: David Chapman, IRB Co-Chair
Subject: Protocol #657
Date: 05/23/2016

Thank you for submitting your research proposal to the St. Catherine University Institutional Review Board (IRB) for review. The primary purpose of the IRB is to safeguard and respect the rights and welfare of human subjects in scientific research. In addition, IRB review serves to promote quality research and to protect the researcher, the advisor, and the university.

On behalf of the IRB, I am responding to your request for approval to use human subjects in your research. Two members of the St. Kate's IRB have read and commented on your application # **657: A comparison of self-selected gait speed, stride length, double-leg stance time, pelvic rotation, and intensity of effort with the use of: no assistive device, a 2-wheeled walker, a 4-wheeled walker, and the "Gaiter" in non-assistive device dependent, community dwelling older adults** as an expedited level review. As a result, the project was approved as submitted.

If you have any questions, feel free to contact me or email via the Mentor messaging system. Also, please note that all research projects are subject to continuing review and approval. You must notify our IRB of any research changes that will affect the risk to your subjects. You should not initiate these changes until you receive written IRB approval. Also, you should report any adverse events to the IRB. **Please use the reference number listed above in any contact with the IRB.**

This approval is effective for one year from this date, 05/23/2016. If the research will continue beyond one year, you must submit a request for IRB renewal before the expiration date. When the project is complete, please submit a project completion form. These documents are available in the St. Catherine University Mentor IRB site.

We appreciate your attention to the appropriate treatment of research subjects. Thank you for working cooperatively with the IRB; best wishes in your research!

Sincerely,

David Chapman, PhD

Co-Chair, Institutional Review Board

ddchapman@stkate.edu

APPENDIX B
Recruitment Flyer

Walker Style: Does It Matter?
St. Catherine University - Doctor of Physical Therapy Program
Research Study
June 2016



Despite the common use of walkers, we know very little about how they actually impact a person's walking. The purpose of this study is to compare the impact of 3 different types of walkers on walking.

This study will focus on *adults over the age of 55 who live in the community and do not currently use a cane or walker.*

This 90-minute study will involve walking without an assistive device and then walking with 3 different types of walkers after a brief training session. A heart rate monitor, as well as a new electronic device, the BTS G-Walk, will be worn to gather the desired data.

Are you interested in participating?
If so, by Friday, June 3, please contact:
Prof. Deborah A. Madanayake @ 651-690-7787

Appendix C
Information and Consent Form

ST CATHERINE UNIVERSITY
Informed Consent for a Research Study

Study Title: The impact of walker style on gait characteristics in older adults

Introduction:

You are invited to participate in a research study investigating how different types of walkers impact walking. This study is being conducted by Doctor of Physical Therapy student researchers (Matthew Bennett, Taylor Hutchins, Kaci Platz) under the supervision and direction of faculty researchers Assistant Professor Deborah A. Madanayake (Doctor of Physical Therapy Program) and Professor Marcella Myers (Biology) at St. Catherine University in St. Paul, MN. You were selected as a possible participant in this research because you walk by yourself without an assistive device in the community and you have expressed an interest in this study. Please read this form and ask questions before you agree to be in the study.

Background Information:

The purpose of this study is to measure the effect of three different walker styles on your walking. This study will look at four separate conditions: walking without a walker, with a 2-wheeled walker, with a 4-wheeled walker, and with a novel assistive device named the “Gaiter”. Approximately 50 people are expected to participate in this research.

Procedures:

If you meet the research subject criteria and agree to be in this study, you will be asked to participate in the following process:

Step 1: Welcome / Screening (Time: 15 minutes)

We will describe this research study, review this consent form, and ask for your informed consent before proceeding. If you choose to participate, a researcher will visually screen your walking for any abnormalities, and record your height, weight, leg length, birth year, and gender.

Step 2: Instruction (Time: 15 minutes)

Next you will be introduced to three different types of walkers: a 2-wheeled walker, a 4-wheeled walker, and the “Gaiter”. You will also be introduced to the BTS G-Walk data gathering device. This device measures your walking characteristics. It is worn around the waist. You will also be introduced to the Polar Team2 heart rate monitor. This device is worn around the chest and measures heart rate.

Step 3: Preparation (Time: 5 minutes)

At this point, you will be asked to step behind a privacy screen so that you can be fitted with an elastic chest strap that contains a heart rate monitor. You will also be fitted with a waist belt that contains the BTS G-Walk device that fits against the low back area. Both devices will send data wirelessly to laptop computers.

Step 4: Data gathering (Time: 45 minutes)

Next you will be asked to walk three times down a 90-foot pathway (gym floor) at a comfortable, self-selected speed, under each of the following conditions:

- 1) with no assistive device
- 2) with a 2-wheel walker
- 3) with a 4-wheel walker
- 4) with the “Gaiter” walker

When using any of the three walkers, you will have a transfer belt around your waist and a researcher will stand just to the side and behind you to ensure your safety. At the end of each 90-foot pathway, you will sit in a chair to rest until you feel ready for another trial.

[Note: Before you use any of the walkers, you will be asked to view a 45-60 second instructional video explaining how to properly use the walker. You will also receive verbal/visual training as needed to ensure that you are using the device safely. You will determine when you are ready to be tested.]

Step 5: Thank-you (Time: 10 minutes)

In conclusion, we will answer any questions you may have, as well as thank you for your participation in this study.

Overall, this study will take approximately 90 minutes of your time.

Risks and Benefits of Being in the Study:

The study has several risks. First, there is a potential fall risk during the study. In order to reduce this risk, you will be trained in how to safely use each of the three walkers. You will also wear a transfer belt around your waist and have someone standing near you at all times when using the three walkers. The assister will be a Doctor of Physical Therapy student, or a physical therapist, all of whom are skilled in assisting persons with walking/balance difficulties, as well as in training people how to use assistive devices for walking. If at any time you become fearful of falling, or if you become tired, or should you in any other way feel uncomfortable, you may terminate your participation in the study.

You will not be compensated for participating in this study. The benefits of participation do not extend beyond the fact that you will have an opportunity to learn about and use three different types of walkers: a 2-wheeled walker, a 4-wheeled walker, and a newly designed walker called the “Gaiter”. It is not the intent of this study to

determine whether or not any of these walkers are safe for your use, nor to prescribe them.

In the event that this research activity results in an injury, such as that resulting from a fall, we will assist you in obtaining medical attention. Any medical care for research-related injuries should be paid by you or your insurance company. If you think you have suffered a research-related injury, please let the researchers know right away.

Confidentiality:

At the time of your participation in this study, all gathered data will be de-identified, meaning it will be linked to a code so as not be traceable back to you. Any information obtained in connection with this research study that can be identified with you, namely this consent form and a document with your name and assigned code, will be kept confidential. In any written reports or publications, you will not be identified or identifiable; only group data will be presented.

If it becomes useful to disclose any of your information, we will seek your permission and tell you the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure; you will have the right to grant or deny permission for this to happen. If you do not grant permission, the information will remain confidential and will not be released.

Signed consent forms and the document with your name and assigned code will be kept in a locked file cabinet in a locked office at St. Catherine University. Electronic data from the BTS G-Walk and Polar Team2 heart rate monitor will be kept on password protected, encrypted computers in St. Catherine University's WHIR Center. Only the student researchers (named above), the faculty advisors (named above), and equipment/software supporter, Alvina Brueggemann, PhD, Program Coordinator of the WHIR Center, will have access to the electronic data. We will finish analyzing the data by June 1, 2017.

Voluntary Nature of the Study:

Participation in this study is completely voluntary. If you decide you do not want to participate in this study, please feel free to say so, and do not sign this form. If you decide to participate in this study, but later change your mind and want to withdraw, simply notify Assistant Professor Deborah A. Madanayake at 651-690-7787 and you will be removed immediately. Your decision of whether or not to participate will have no negative or positive impact on your relationship with St. Catherine University, nor with any of the students or faculty involved in the research.

Contacts and Questions:

If you have any questions, please feel free to contact Assistant Professor Deborah A. Madanayake at 651-690-7787. You may ask questions now, or if you have any additional questions later I will be happy to answer them. If you have other questions

or concerns regarding the study and would like to talk to someone other than the researcher(s), you may also contact Dr. John Schmitt, Chair of the St. Catherine University Institutional Review Board, at (651) 690-7739 or jsschmitt@stkate.edu.

You may keep a copy of this form for your records.

Statement of Consent:

I consent to participate in the study. My signature indicates that I have read this information and my questions have been answered. I also know that even after signing this form, I may withdraw from the study by informing the researcher(s).

Signature of Participant

Date

Signature of Researcher

Date

APPENDIX D

Welcome / Screening Form Subject ID: _____ Birth
 Year _____ Gender: M / F

INSTRUCTIONS FOR RESEARCHERS:

- Wear nametag; introduce self; give overview of the research study
- Verbally and visually go through consent form; to assess understanding ask to summarize for you what it is he/she will be asked to do and ask to explain back what would happen if he/she withdraws from the study (stress that he/she may withdraw at any time without consequence)
- If subject consents, obtain signature on form; leave a copy (must obtain consent before proceeding); otherwise thank for time and leave faculty business card – invite subject to call if any questions or to further discuss study
- Following consent, perform the following screens to determine eligibility and baseline status

Screen	Instructions for Screener	Results
Verbal Questions	-Verbally inquire: <ul style="list-style-type: none"> • “What is your age?” [age ≥ 55 years?] • “Have you used a walker, cane, or crutches within the past 12 months?” • “Do you have a history of a joint replacement, stroke or other neurological conditions, or surgery on your legs within past 12 months?” • “Do you have a pacemaker or other electronic implant?” 	_____yes _____no* _____yes* _____no _____yes* _____no _____yes* _____no *exclusion criterion
Gait	-Visually observe subject’s gait for asymmetries or abnormal gait quality -Subject to walk away from observer and then back toward observer (minimum 20 feet)	___ Normal ___ Abnormal* *exclusion criterion
Height	-Subject to stand with back to wall containing tape measure	

	-Heels against wall -Ruler with leveler on top of head to determine height on tape measure	_____ cm
Leg Length	-Measure leg length with flexible tape measure, from greater trochanter to floor without shoes (right leg)	_____ cm
Weight	-Verbally inquire “ <i>What is your approximate weight?</i> ”	_____ lbs

APPENDIX E
Gaiter



