Effects of Ambulatory Assistive Devises on Subjects Post-CVA: A Series of Case Studies

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EFFECTS OF AMBULATORY ASSISTIVE DEVICES ON SUBJECTS POST-CVA:
A SERIES OF CASE STUDIES

by

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University of North Dakota, 2005

A Scholarly Project
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Doctor of Physical Therapy

Grand Forks, North Dakota
May
2007
This Scholarly Project, submitted by David Fulton and Richard Zaruba in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

[Signature]
(Graduate School Advisor)

[Signature]
(Chairperson, Physical Therapy)
PERMISSION

Title Effects of Ambulatory Assistive Devices on Subjects Post-CVA: A Series of Case Studies

Department Physical Therapy

Degree Doctor of Physical Therapy

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Signatures

Date 12/18/06
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ACKNOWLEDGMENT

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Finally, we would like to thank our family and friends for their encouragement and support over the last 3 years. They have contributed more than they realize towards our success. Their support has been very important throughout not only this study, but though our entire academic and professional development.
ABSTRACT

The purpose of this study was to determine if regularly ambulating with and without an ambulatory assistive device will lead to differences in the spatiotemporal and kinematic parameters of gait demonstrated by the subjects status post cerebral vascular accident. This study was comprised of a series of three case studies. All subjects were a minimum of fifty years old, at least three months status post cerebral vascular accident, capable of effectively communicating with researchers, and in good health. Ambulation criteria for inclusion were to regularly ambulate independently for 50 feet without use of an ambulatory assistive device, and regularly ambulate for an extended distances (at least 100") with an ambulatory assistive device. Gait was assessed using observational gait analysis and the GAITRite® system. The GAITRite® system is an electronic walkway, which collects the spatiotemporal parameters of gait. None of the subjects demonstrated major alterations in kinematic gait parameters between when an ambulatory assistive device was used and not used. The only consistent deviation noted was a decrease in cadence (walker -12.1%, cane -5.9%) and velocity (walker -11.3%, cane -6.5%) when an ambulatory assistive device was used in conjunction with an increase in step time (walker 14.9%, cane 5.7%) and cycle time (walker 13.6%, cane 6.4%). However, all subjects indicated feelings of increased safety when using an ambulatory assistive device. While the beneficial effects are as yet undetermined, there would appear to be no detrimental effects of ambulating. Further research is required to substantiate these results.
CHAPTER I
INTRODUCTION

Normal ambulation is typified by a smooth forward progression of an individual’s center of gravity with well-coordinated movement of the limbs and torso. The ambulation of a subject with hemiplegia has been characterized as slow, fatiguing, and uncoordinated to a varying degree between individuals. Differences observed in the gait patterns associated with hemiplegia are vaguely characterized and may vary widely between individuals. These differences may have a substantial affect on any of the currently identified parameters of the gait pattern. Additionally, the ambulation of subjects with hemiplegia often require use of an ambulatory assistive device, such as a cane or front wheeled walker for ambulation at home and/or in the community. While the use of an ambulatory assistive device is believed to have an affect on the gait pattern of these individuals little research has been conducted in this area.

Hemiplegic Gait

While there is a small amount of variation in the gait pattern of normal individuals, these are small in comparison to the variation demonstrated among subjects with hemiplegia. This is reportedly due to the variation in diagnosis, functional recovery, individual muscle substitution patterns, and methods of research used. It was hypothesized by Perry that the gait deviations observed in subjects with hemiplegia are the result of insufficient single-limb balance and control of forward...
progression. Subjects that were studied demonstrated four gait deficits, lack of shock absorption at heel strike, deficient momentum control during stance phase, weak or absent push-off to maintain forward momentum, and inadequate excursion of the affected limb during the swing phase. These observations were supported and expanded upon in subsequent research and studies that have been conducted.

*Spatiotemporal Components*

The most common gait deviation reported in subjects with hemiplegia is a decrease in velocity. The normal speed, cadence, and stride length for a male are approximately 1.3-1.6 m/s, 110-115 steps/min, and 1.4-1.6 m respectively. The majority of subjects with hemiplegia display a much lower velocity ranging from 0.43 ± 0.31 m/s. This can be attributed to significant deviations in a number of spatiotemporal gait parameters including decreased stride length (0.77 ± 0.28 m/cycle) and cadence (0.52 ± 0.20 cycle/s). The resulting velocity differences were found to be unrelated to subject age ($R^2 = 0.06; P = NS$), gender ($t = 1.08; P = NS$), side of hemiplegia ($t = 1.46; P = NS$), and duration of stroke ($R^2 = 0.13; P = NS$).

Significant differences in gait phases were also reported in relationship to gait asymmetry between the affected and non-affected sides. Normal individuals display approximately 38% swing phase and 62% stance phase, with stance phase divided into 24% double-leg support and 38% single-leg support on each leg. It was observed that subjects with hemiplegia demonstrated increased stance phase (74 ± 8%) and decreased swing phase (26 ± 9%) on the affected side, and a significantly longer stance phase (82 ± 8%) and shorter swing phase (18 ± 9%) on the non-affected side.
Time spent in double-leg and single-leg stance were also significantly different with double-leg stance averaging 52 ± 17% of the gait cycle.¹⁴

*Joint Kinematics*

As with all gait parameters, the kinematic components vary greatly between individuals with hemiplegia.⁶⁻⁸,²² Common patterns of asymmetry displayed by subjects with hemiplegia include hip flexion, knee extension, ankle plantar flexion, and lower limb circumduction during swing; hip flexion, limited knee flexion, and ankle plantar flexion during loading; knee hyperextension during mid-stance; and lack of roll-off during toe-off.²,⁹,¹¹

Limited range of motion in the hip, knee, and ankle often results in the typical stiff legged gait reported in previous studies.²,⁹,¹¹ Limited dorsiflexion and knee flexion may contribute to the circumduction of the affected lower extremity during the swing phase of the gait cycle. An asymmetric follow through by the affected limb during the swing phase is also common secondary to limited dorsiflexion and knee flexion and may result in the characteristic asymmetric gait pattern previously reported in the literature.¹,¹²,²²,²³ Limited dorsiflexion with excessive plantar flexion and limited ankle strength often leads to alterations in all phases of the gait cycle. This effect is most noticeable in initial contact and toe-off through initial swing.²,⁹,¹¹⁻¹³,²⁴,²⁵ Swing phase was often initiated by flexion of the entire lower extremity on the affected side,⁹,¹⁸,²⁴,²⁶ as opposed to the sequential activation of hip, knee, and ankle seen in normal individuals.²¹,²⁷ These deviations are directly related to the deviations seen in the spatiotemporal described previously, and kinetic aspects of gait including push-off.²,⁹,¹²,¹³,¹⁸,²⁸
Hemiplegic Gait with an Ambulatory Assistive Device

It is common practice to provide subjects with hemiplegia with ambulatory assistive device as needed for functional mobility.\textsuperscript{29} However, certain schools of thought believe that providing subjects with ambulatory assistive device is counter productive and may lead to additional gait and posture abnormalities.\textsuperscript{30-32} While this school of thought is somewhat prevalent, it has failed to be demonstrated in the previous studies and research that was found.\textsuperscript{4, 5, 25, 33} Current practice guidelines are to provide the least amount of support and assistance required often in the form of a cane, single-point or quad, or a front-wheeled walker for functional ambulation.\textsuperscript{29}

\textit{Hemiplegic Gait with a Cane}

It has been widely theorized that use of a cane (single-point or quad) in subjects with hemiplegia would result in significant asymmetries in gait.\textsuperscript{30-32} These assertions have not been found to be valid in the limited research that has been conducted at this time. In direct opposition to these assertions, research has actually found less deviation in spacial parameters with a cane than without.\textsuperscript{4, 5, 25, 33, 34} Differences demonstrated during the use of a cane were significantly increased stride period, stride length, and affected side step length, as well as decreased cadence and step width in comparison with those who walked without a cane.\textsuperscript{34} Use of a cane was found to improve the hemiplegic gait by assisting the affected limb to smoothly shift the center of body mass toward the sound limb and to enhance push off during pre-swing phase. Improvements were also demonstrated in circumduction gait during swing phase.\textsuperscript{34} Also, no relationship was found between use of an ambulatory assistive device and support, walking ability or trunk movements was demonstrated in the literature.\textsuperscript{4, 5, 25, 33} A difference has been shown
between use of a single-point cane and a quad cane with the quad cane decreasing the both spatiotemporal and kinematic parameters of gait.\textsuperscript{33-36} The factor that was found to be related to support, walking ability or trunk movements was the severity of the hemiplegia.\textsuperscript{5}

\textit{Hemiplegic Gait with a Walker}

While use and issuance of a walker, particularly a front-wheeled walker, is common, there is little research as to the affects of its use. Similar results were found with the use of a standard walker as the results found with the use of the cane.\textsuperscript{4, 5, 33} The walker also was shown to decrease lateral movement of the hips during gait, which was attributed to the bilateral support provided.\textsuperscript{5} Both standard walkers and front-wheeled walkers were noted to decrease gait velocity more than the use of a cane with corresponding decreases in cadence, step length bilaterally, and stride length, and increases in single-leg stance on the affected limb.\textsuperscript{4, 5, 33} Wheeled walkers have been found to be more effective in subjects than non-wheeled walkers, when appropriate for the subject, improving the spatiotemporal parameters of gait.\textsuperscript{37}

Problem Statement/Hypothesis

The available research demonstrates some variation between gait when an ambulatory assistive device is used and when one is not. Further, it shows some variation between gait when a cane is used versus a front-wheeled walker.\textsuperscript{4, 5, 33-39} The research question to be addressed in this study is “Does regularly ambulating with and without an ambulatory assistive device will lead to differences in the spatiotemporal and kinematic parameters of gait demonstrated by the subjects?” This can be exemplified by subjects that ambulate at home without an ambulatory assistive device, but use an ambulatory
assistive device outside the home in the community. It is a basic concept in motor learning to have carryover from one activity to another, thus it is logical to expect a carryover affect to be present when a subject ambulates with an assistive device transitionally. This leads to the hypothesis of: “Regularly ambulating with and without an ambulatory assistive device will lead to differences of the kinematic and spatiotemporal parameters of gait demonstrated by the subjects.”

Purpose/Significance

The purpose of this study is to explore the possible effects on individuals, status post-cerebral vascular accident, that regularly ambulate with and without an ambulatory assistive device, and its effects on spatiotemporal and kinematic parameters of gait. Clinically, this study will help to define the clinical guidelines used for gait training and utilization of ambulatory assistive device by individuals with hemiplegia.
CHAPTER II

METHODS

Prior to the start of this study, a project proposal was submitted to the University of North Dakota Institutional Review Board (see Appendix) for approval and for use of human subjects for this study (IRB# 200605-385). This proposal included a consent form (see Appendix), and a video and photograph release form (see Appendix).

Subjects

Subjects were recruited by word of mouth with the assistance of UND professors and physical therapists in the surrounding community. Subjects were required to be a minimum of fifty years old, at least three months status post cerebral vascular accident, capable of effectively communicating with researchers, and in good health. Ambulation criteria for inclusion were to regularly ambulate independently for 50 feet without use of an ambulatory assistive device, and regularly ambulate for an extended distances (at least 100’) with an ambulatory assistive device. Recruitment of subjects took place from June 1, 2006 through November 12, 2006.

Instrumentation

Two methods of gait assessment were selected for the study, observational gait analysis and the GAITRite® system (CIR Systems Inc., 1625 East Darby Road, Havertown, PA 19083). Observational gait analysis was selected to collect kinematic data for each subject’s gait. The GAITRite® system was selected to collect the
Figure 1. GAITRite® Walkway. Note output boxes to right.
spatiotemporal data for each subject’s gait. The ability to compare and contrast kinematic and spatiotemporal data from each subject’s gait allows for an increased understanding of the deviations and differences detected. The researchers were trained in the proper use of the GAITRite® system under the direction of their advisor, a licensed physical therapist with over 20 years of experience, and trained in observational gait analysis in previous course work and clinical affiliations.

Observational Gait Analysis

Observational gait analysis is a qualitative tool, which is commonly employed by physical therapists in the clinical setting.²⁰,⁴⁰ It is used to collect qualitative data regarding the movement of the body from both a functional and kinematic standpoint. While commonly employed by health care professionals, validity and reliability between raters has been called into question.⁴⁰,⁴¹ Despite this drawback, data gathered can be an important tool in interpreting and understanding the spatiotemporal data gathered, particularly when combined with other methods of gait assessment.²⁰

GAITRite® system

The GAITRite® system is an electronic walkway that automates the collection of spatial and temporal parameters of gait.⁴²,⁴³ The standard GAITRite® system electronic walkway contains six sensor pads encapsulated in a roll-up carpet, to produce an active area 28 inches wide and 16 feet long. In this arrangement, the active area is a grid with dimensions of 48 sensors by 384 sensors, placed on 0.5-inch centers. The 16-foot walkway is portable, can be laid over any flat surface, requires minimum setup and collection time, and does not require the placement of any devices on the subject. As the subject ambulates across the walkway, the system captures the relative arrangement, the
geometry and the applied pressure, of each footfall as a function of time. The application software (GAITRite® version 3.4ne with Goldwalking, set at a sample rate of 80 Hz) controls the functionality of the walkway, processes the raw data into footfall patterns, and computes the temporal and spatial parameters. The software stores each walk by subject and supports a variety of reports and analyses. The system can be utilized to test subjects with or without shoes and assistive devices.

The validity of the GAITRite® system has been supported by studies in adults comparing clinical gait assessment techniques including footprint studies, using shoe switches, and more technologically advanced techniques such as kinematic assessments. Interclass correlation coefficient (ICC) reported for spatial parameters, including step length and stride length ranged from 0.97 to 0.99 with lower ICCs (0.61–0.67) for step time and stride time. Comparison of two-dimensional video analysis with the GAITRite® system revealed high correlation (0.94–1.0) for step length, step time, stride velocity, stance duration, and swing duration. However, with increasing speeds greater differences were noted for spatial gait parameters including step length and stride velocity. These differences may be related to differences in the method used to identify the initiation of a foot fall. Inter-trial reliability for walking speed, cadence, and step length at preferred and fast speeds in adults ranged from good to excellent (ICCs 0.76–0.97) and was slightly lower at slower speeds.

Procedure

The subjects were contacted via phone and given a verbal explanation of the testing to be performed and asked if they would be interested in participating. If interested, the subjects were asked to come to the Physical Therapy department at the
UND School of Medicine to read and sign informed consent and video releases forms (See Appendix), and then participate in the study. A copy of the consent form was given to the subject. Subjects were initially interviewed about their medical history and ambulation at home and in the community. Subjects were then asked to walk across the GAITRite® system walkway at their normal walking pace wearing their everyday shoes. Subjects started at designated point 6 feet before the walkway, and finished at designated point 6 feet after the walkway to minimize the affects of acceleration and deceleration on the data gathered. Two preliminary walks were performed initially to familiarize subjects with the surface. If the walk was disturbed by external influences, such as output boxes or abrupt noises, the subjects were asked to repeat walk. Subjects performed a minimum of 10 trials, walking 28 feet per trial. They walked a minimum of 5 times with and 5 times without their ambulatory assistive device. Five walks were chosen to allow for a minimum of twenty footfalls to be recorded and analyzed. Researchers did not alter subjects gait or assistive devices during gait. Breaks were taken for 2-3 minutes between trials and as needed or requested by subjects. Observational gait analysis was conducted on subjects both visually during walks and on video tape by researchers. The researchers were under the supervision of their advisor or a licensed physical therapist and were the only people to carry out the research procedures. Results of the procedures were discussed with each subject at the conclusion of the procedures.

Data Analysis

Observational gait analysis was conducted on each subject by two researchers. Observations for kinematic parameters of gait were recorded by the researchers for each
of the following anatomical areas: upper extremities, trunk, hips, knees and ankles. Observations were then compared between researchers and summarized for final results.

Raw data from each walk was processed prior to analysis by the GAITRite® system. The first and last steps were removed along with any data from ambulatory assistive device from the graphic representation of the walk. Walks were then visually analyzed for presence of deviation in steps and then consolidated into specific tests, each containing a minimum of twenty footfalls.

Statistical data were obtained from the GAITRite® system for ambulation with and without and an ambulatory assistive device for each subject. The means of gait parameters gathered by the GAITRite® system program were compared and contrasted for each subject using Microsoft Excel (Microsoft Corp., One Microsoft Way, Redmond, WA 98052-6399). Results were tabled for each subject showing the means, differences, and percent difference.

Reporting of Results

The results obtained in this study were submitted to fulfill the requirements of the scholarly project for the Doctorate of Physical Therapy degree at the University of North Dakota. The results will be submitted to the faculty preceptor, and will be available in the Harley E. French Library at the University of North Dakota School of Medicine and Health Science.
CHAPTER III

RESULTS

Only three subjects met the inclusion criteria of this study. Many of the subjects screened failed to utilize an ambulatory device regularly if at all. Data requirements of a minimum of 20 footfalls per ambulatory condition were also met by these subjects allowing for a basic comparison of gait parameters.

Subject One

Subject One was a 75-year-old male that suffered a left cerebral vascular accident approximately five years prior to testing. No significant medical history was noted other than the occurrence of the cerebral vascular accident. The incident has resulted in right hemiplegia with loss of range of motion and strength in shoulders bilaterally, and the right hip. The subject reported the ability to ambulate without ambulatory assistive device for a distance of 200 feet. He indicated that his front-wheeled walker is used for community ambulation and in cases of fatigue. He reported that the use of a front-wheeled walker gives him a greater sense of balance and safety during ambulation.

Visual Assessment

Subject One demonstrated a decreased reciprocal swing of upper extremity bilaterally during ambulation without his walker. Minimal trunk rotation was observed in the subject during all walking trials with or without an ambulatory assistive device. An asymmetric and hesitant gait pattern was noted during trials with or without an
ambulatory assistive device. A decrease in hip and knee flexion and velocity was noted on the affected side. Limited step through on affected side was also observed. Limited dorsiflexion was noted on affected side resulting in increased external rotation of the extremity.

*GAITRite® System Evaluation*

Eighty-four steps were captured for data without the use of the front-wheeled walker, and eighty-two steps were captured with the use of a front-wheeled walker. Footfalls captured by the GAITRite® system demonstrate a footfall pattern consistent with an asymmetric gait displaying a shortened follow through of the right affected lower extremity during swing phase. Figure 2 and 3.

![Figure 2. Subject One without walker.](image)

![Figure 3. Subject One with walker.](image)

* Left footfall in teal and right footfall in purple with footfalls number in sequence of steps. Note that right foot stops with heel next to the forefoot of the left foot, causing asymmetric stepping pattern.

The data obtained from ambulation without and with a front-wheeled walker and its comparison for differences are found in Table 1. There were notable differences in velocity (-9.9%), cadence (-12.2 %), step time (left 17.4%, right 11.7%), and cycle time (left 13.1%, right 14.2%) bilaterally when using a front-wheeled walker. Differences were found in step length (11.2%) on right.
Table 1. Subject One: No Ambulatory Assistive Device versus Walker Comparison

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Left</th>
<th>Right</th>
<th>%</th>
<th>Left</th>
<th>Right</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Velocity (cm/sec)</td>
<td>None 42.60</td>
<td>Walker 38.40</td>
<td>-4.20</td>
<td>-9.9%</td>
<td>None 42.60</td>
<td>Walker 38.40</td>
</tr>
<tr>
<td>Cadence (Step/M)</td>
<td>113.60</td>
<td>99.70</td>
<td>-13.90</td>
<td>-12.2%</td>
<td>113.60</td>
<td>99.70</td>
</tr>
<tr>
<td>Step Time (sec)</td>
<td>0.46</td>
<td>0.54</td>
<td>0.08</td>
<td>17.4%</td>
<td>0.60</td>
<td>0.67</td>
</tr>
<tr>
<td>Cycle Time (cm)</td>
<td>1.07</td>
<td>1.21</td>
<td>0.14</td>
<td>13.1%</td>
<td>1.06</td>
<td>1.21</td>
</tr>
<tr>
<td>Step Length (cm)</td>
<td>32.09</td>
<td>31.10</td>
<td>-0.99</td>
<td>-3.1%</td>
<td>12.88</td>
<td>14.32</td>
</tr>
<tr>
<td>Stride Length (cm)</td>
<td>45.62</td>
<td>45.59</td>
<td>-0.03</td>
<td>-0.1%</td>
<td>44.93</td>
<td>45.56</td>
</tr>
<tr>
<td>Base Support (cm)</td>
<td>12.81</td>
<td>12.43</td>
<td>-0.38</td>
<td>-3.0%</td>
<td>12.84</td>
<td>12.46</td>
</tr>
<tr>
<td>Single Leg (%)</td>
<td>36.10</td>
<td>35.70</td>
<td>-0.40</td>
<td>-1.1%</td>
<td>26.60</td>
<td>25.90</td>
</tr>
<tr>
<td>Double Leg (%)</td>
<td>37.50</td>
<td>38.10</td>
<td>0.60</td>
<td>1.6%</td>
<td>36.50</td>
<td>38.30</td>
</tr>
<tr>
<td>Swing Phase (%)</td>
<td>26.40</td>
<td>25.90</td>
<td>-0.50</td>
<td>-1.9%</td>
<td>36.40</td>
<td>35.70</td>
</tr>
<tr>
<td>Stance Phase (%)</td>
<td>73.70</td>
<td>74.00</td>
<td>0.30</td>
<td>0.4%</td>
<td>63.60</td>
<td>64.30</td>
</tr>
<tr>
<td>Step/Ext Ratio</td>
<td>0.39</td>
<td>0.38</td>
<td>-0.01</td>
<td>-2.6%</td>
<td>0.16</td>
<td>0.18</td>
</tr>
<tr>
<td>Toe In/Out (deg)</td>
<td>4.00</td>
<td>3.00</td>
<td>-1.00</td>
<td>-25.0%</td>
<td>13.00</td>
<td>13.00</td>
</tr>
</tbody>
</table>

Subject Two

Subject Two was a 59-year-old male that suffered a left cerebral vascular accident approximately eighteen months prior to testing. No significant medical history was noted prior to the cerebral vascular accident. The incident has resulted in right hemiplegia with loss of strength and the presence of spasticity in both the upper and lower extremities, for which he had received Botox injections approximately four months prior to testing. Spouse assisted subject with communication as needed due to global aphasia and difficulty with articulation. He reported the ability to ambulate without ambulatory assistive device for a distance of 250 foot, and indicated that his single-point cane was used for community ambulation and in cases of fatigue. He also reported that the use of the single-point cane gave him a greater sense of balance and safety during ambulation. Additionally, he reported that fatigue occurs at shorter distances when he does not wear the ankle-foot orthotic for his right lower extremity. Use of a wheelchair was reported for extended distances secondary to fatigue. Subject Two was not wearing his ankle-foot orthotic on his right lower extremity when data were obtained during his walking trials.
Visual Assessment

Subject Two demonstrated an impaired reciprocal swing of upper extremity on affected side secondary to lack of muscle tone and capsular pattern present in shoulder. When ambulating with a cane the subject utilized it to decrease his momentum and catch himself during swing phase of the on-affected side, prior to initial contact. Subject Two walked with the affected side positioned forward and no reciprocal trunk rotation. An asymmetric gait pattern was present during ambulation with and without the use of his cane. Advancing the lower affected extremity required the subject to lean his torso backward, hike hip, and circumduct the extremity secondary to limited strength. Limited movement was noted in the knee with hyperextension utilized during single leg stance on affected side. The lower extremity was noted to be internally rotated with limited dorsiflexion of the ankle employed during gait on affected side. The lower extremity on non-affected side was observed to compensate for lack of control with eccentric hip and knee extension during the loading response, and concentric hip and knee extension for advancement of affected lower extremity. (See CD-ROM in back cover)

GAITRite® System Evaluation

Fifty-two steps were captured for data without the use of the cane, and fifty-eight steps were captured with the use of a cane. Footfalls captured by the GAITRite® system demonstrate a footfall pattern consistent with a high arch on the right lower extremity. The footfall pattern also demonstrated an asymmetric gait displaying a shortened follow through with the left non-affected lower extremity during swing phase, and a longer step forward with the right affected lower extremity during swing phase. Figures 4 and 5.
* Left footfall in teal and right footfall in purple with footfalls number in sequence of steps. Note that left foot stops with heel next to the forefoot of the right foot, causing asymmetric stepping pattern. Also, note that arch is incomplete on right footfalls indicating subject is ambulating with weight shifted to lateral edge of foot.

The data obtained from ambulation with and without a cane and its comparison for differences are found in Table 2. There were notable differences in velocity (-5.9%), cadence (-6.9%), heel-to-heel base of support (left -13.4%, right -12.8%), cycle time (left 6.6%, right 7.4%), swing phase (left 9.6%, right -6.9%) bilaterally when using a cane. Unilaterally differences were found in step time (18.9%), and step length (9.3%) on left lower extremity.

Table 2. Subject Two: No Ambulatory Assistive Device versus Cane Comparison

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Left</th>
<th>Right</th>
<th>Diff</th>
<th>%</th>
<th>None</th>
<th>Cane</th>
<th>Diff</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Velocity (cm/sec)</td>
<td>47.80</td>
<td>45.00</td>
<td>-2.80</td>
<td>-5.9%</td>
<td>47.80</td>
<td>45.00</td>
<td>-2.80</td>
<td>-5.9%</td>
</tr>
<tr>
<td>Cadence (Steps/M)</td>
<td>101.60</td>
<td>94.60</td>
<td>-7.00</td>
<td>-6.9%</td>
<td>101.60</td>
<td>94.60</td>
<td>-7.00</td>
<td>-6.9%</td>
</tr>
<tr>
<td>Step Time (sec)</td>
<td>0.37</td>
<td>0.44</td>
<td>0.07</td>
<td>18.9%</td>
<td>0.84</td>
<td>0.86</td>
<td>0.02</td>
<td>2.4%</td>
</tr>
<tr>
<td>Cycle Time (cm)</td>
<td>1.22</td>
<td>1.30</td>
<td>0.08</td>
<td>6.6%</td>
<td>1.22</td>
<td>1.31</td>
<td>0.09</td>
<td>7.4%</td>
</tr>
<tr>
<td>Step Length (cm)</td>
<td>14.65</td>
<td>16.01</td>
<td>1.36</td>
<td>9.3%</td>
<td>44.8</td>
<td>43.33</td>
<td>-1.47</td>
<td>-3.3%</td>
</tr>
<tr>
<td>Stride Length (cm)</td>
<td>58.93</td>
<td>59.50</td>
<td>0.57</td>
<td>1.0%</td>
<td>59.04</td>
<td>59.69</td>
<td>0.65</td>
<td>1.1%</td>
</tr>
<tr>
<td>Base Support (cm)</td>
<td>23.30</td>
<td>20.17</td>
<td>-3.13</td>
<td>-13.4%</td>
<td>22.98</td>
<td>20.05</td>
<td>-2.93</td>
<td>-12.8%</td>
</tr>
<tr>
<td>Single Leg (%)</td>
<td>45.10</td>
<td>42.30</td>
<td>-2.80</td>
<td>-6.2%</td>
<td>17.80</td>
<td>19.30</td>
<td>1.50</td>
<td>8.4%</td>
</tr>
<tr>
<td>Double Leg (%)</td>
<td>37.20</td>
<td>38.30</td>
<td>1.10</td>
<td>3.0%</td>
<td>37.50</td>
<td>37.50</td>
<td>0.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>Swing Phase (%)</td>
<td>17.70</td>
<td>19.40</td>
<td>1.70</td>
<td>9.6%</td>
<td>45.20</td>
<td>42.10</td>
<td>-3.10</td>
<td>-6.9%</td>
</tr>
<tr>
<td>Stance Phase (%)</td>
<td>82.30</td>
<td>80.60</td>
<td>-1.70</td>
<td>-2.1%</td>
<td>54.80</td>
<td>57.90</td>
<td>3.10</td>
<td>5.7%</td>
</tr>
<tr>
<td>Step/Ext Ratio</td>
<td>0.17</td>
<td>0.18</td>
<td>0.01</td>
<td>5.9%</td>
<td>0.50</td>
<td>0.49</td>
<td>-0.01</td>
<td>-2.0%</td>
</tr>
<tr>
<td>Toe In/Out (deg)</td>
<td>26.00</td>
<td>22.00</td>
<td>-4.00</td>
<td>-15.4%</td>
<td>-6.00</td>
<td>-6.00</td>
<td>0.00</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

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Subject Three

Subject Three was a 79-year-old male that suffered a left cerebral vascular accident approximately 22 weeks prior to testing. He had a past medical history significant for type II diabetes, high blood pressure, and hammertoe surgery on his right second toe. The cerebral vascular accident has resulted in right hemiplegia with loss of strength in the right lower extremity. Subject Three reported he regularly ambulated without an assistive device for a distance of 150 feet. He indicated that a front-wheeled walker is used for community ambulation and in cases of fatigue. He also said that he uses his single-point cane or no assistive device at home. The subject reported that the use of an ambulatory assistive device gives him a greater sense of balance and safety during ambulation.

Visual Assessment

Subject Three demonstrated an impaired reciprocal swing of the upper extremity on the affected side secondary to the flexor synergy pattern present during ambulation with and without a cane. A significant decrease in trunk rotation was observed in the subject during all walking trials with and without assistive devices. A decrease in hip and knee flexion was noted on the affected side with significant posting a beginning of double leg stance phase. Lack of dorsiflexion and heel strike was noted on the affected side during gait.

GAITRite® System Evaluation

Twenty-seven steps were captured for data without the use of an ambulatory assistive device, twenty-five steps were captured with the use of a cane, and twenty-four steps were captured with the use of a front wheeled walker. Footfalls captured by the
GAITRite® system demonstrate a footfall pattern with minimal asymmetry and closely approximating a normal gait pattern. Figures 6, 7, and 8.

Figure 6. Subject Three without device.*

Figure 7. Subject Three with cane.*

Figure 8. Subject Three with walker.*

* Left footfall in teal and right footfall in purple with footfalls number in sequence of steps. Note that Subject Three displays lateral weight shift to right as demonstrated by the failure of the left foot to transition weight through left outer forefoot. This pattern appears to be most prevalent with no ambulatory assistive device is used.

The data obtained from ambulation with and without a cane and its comparisons for differences are found in Table 3. There were notable differences in velocity (-7.1%), cadence (-4.9%), and double-leg support (left 7.0%, right 5.6%) bilaterally when using a cane. Unilateral differences were found in step time (9.1%), cycle time (5.4%), and single-leg support (-8.0%) on right lower extremity; and swing phase (-7.4%) on the left lower extremity. Toe in/out differences were found bilaterally with the left lower extremity demonstrating an additional 2° toe in (66.7%), and the right lower extremity demonstrating an additional 5° toe out (38.5%).
Table 3. Subject Three: No Ambulatory Assistive Device versus Cane Comparison

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>None</th>
<th>Cane</th>
<th>Diff</th>
<th>%</th>
<th>None</th>
<th>Cane</th>
<th>Diff</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Velocity (cm/sec)</td>
<td>66.50</td>
<td>61.80</td>
<td>-4.70</td>
<td>-7.1%</td>
<td>66.50</td>
<td>61.80</td>
<td>-4.70</td>
<td>-7.1%</td>
</tr>
<tr>
<td>Cadence (Steps/M)</td>
<td>92.50</td>
<td>88.00</td>
<td>-4.50</td>
<td>-4.9%</td>
<td>92.50</td>
<td>88.00</td>
<td>-4.50</td>
<td>-4.9%</td>
</tr>
<tr>
<td>Step Time (sec)</td>
<td>0.64</td>
<td>0.65</td>
<td>0.01</td>
<td>1.6%</td>
<td>0.66</td>
<td>0.72</td>
<td>0.06</td>
<td>9.1%</td>
</tr>
<tr>
<td>Cycle Time (cm)</td>
<td>1.31</td>
<td>1.37</td>
<td>0.06</td>
<td>4.6%</td>
<td>1.30</td>
<td>1.37</td>
<td>0.07</td>
<td>5.4%</td>
</tr>
<tr>
<td>Step Length (cm)</td>
<td>45.11</td>
<td>43.86</td>
<td>-1.25</td>
<td>-2.8%</td>
<td>41.01</td>
<td>40.18</td>
<td>-0.83</td>
<td>-2.0%</td>
</tr>
<tr>
<td>Stride Length (cm)</td>
<td>87.37</td>
<td>84.43</td>
<td>-2.94</td>
<td>-3.4%</td>
<td>85.73</td>
<td>83.82</td>
<td>-1.91</td>
<td>-2.2%</td>
</tr>
<tr>
<td>Base Support (cm)</td>
<td>15.03</td>
<td>15.71</td>
<td>0.68</td>
<td>4.5%</td>
<td>15.23</td>
<td>15.47</td>
<td>0.24</td>
<td>1.6%</td>
</tr>
<tr>
<td>Single Leg (%)</td>
<td>31.70</td>
<td>31.70</td>
<td>0.00</td>
<td>0.0%</td>
<td>31.10</td>
<td>28.60</td>
<td>-2.50</td>
<td>-8.0%</td>
</tr>
<tr>
<td>Double Leg (%)</td>
<td>37.10</td>
<td>39.70</td>
<td>2.60</td>
<td>7.0%</td>
<td>37.60</td>
<td>39.70</td>
<td>2.10</td>
<td>5.6%</td>
</tr>
<tr>
<td>Swing Phase (%)</td>
<td>30.90</td>
<td>28.60</td>
<td>-2.30</td>
<td>-7.4%</td>
<td>32.00</td>
<td>31.80</td>
<td>-0.20</td>
<td>-0.6%</td>
</tr>
<tr>
<td>Stance Phase (%)</td>
<td>69.10</td>
<td>71.40</td>
<td>2.30</td>
<td>3.3%</td>
<td>68.00</td>
<td>68.20</td>
<td>0.20</td>
<td>0.3%</td>
</tr>
<tr>
<td>Step/Ext Ratio</td>
<td>0.48</td>
<td>0.47</td>
<td>-0.01</td>
<td>-2.1%</td>
<td>0.44</td>
<td>0.43</td>
<td>-0.01</td>
<td>-2.3%</td>
</tr>
<tr>
<td>Toe In/Out (deg)</td>
<td>-3.00</td>
<td>-5.00</td>
<td>-2.00</td>
<td>66.7%</td>
<td>13.00</td>
<td>18.00</td>
<td>5.00</td>
<td>38.5%</td>
</tr>
</tbody>
</table>

The data obtained from ambulation with and without a walker and its comparison for differences are found in Table 4. There were notable differences in velocity (-12.8%), and cadence (-12.1%), step time (left 9.4%, right 18.2%), cycle time (left 13.0%, right 13.1%), heel-to-heel base of support (left -12.0%, right -12.8%), and double-leg support (left 9.4, right 7.7%) bilaterally when using a front-wheeled walker. Unilaterally differences were found in single-leg support (-7.4%) on right lower extremity, and swing phase (-7.1%) on the left lower extremity. Toe in/out differences were found bilaterally with the left lower extremity demonstrating an additional 3° toe in (100%), and the right lower extremity demonstrating an additional 2° toe out (15.4%).

The data obtained from ambulation with and without a cane and its comparison for differences are found in Table 5. There were notable differences in velocity (-6.1%), cadence (-7.6%), step time (left 7.7%, right 8.3%), cycle time (left 8.0%, right 7.3%) and heel-to-heel base of support (left -15.8%, right -14.2%) bilaterally when using a front-wheeled walker. No unilateral differences were found that were greater than 5%.

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Table 4. Subject Three: No Ambulatory Assistive Device versus Walker Comparison

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Left</th>
<th></th>
<th>Right</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
<td>Walker</td>
<td>Diff</td>
<td>%</td>
</tr>
<tr>
<td>Velocity (cm/sec)</td>
<td>66.50</td>
<td>58.00</td>
<td>-8.50</td>
<td>-12.8%</td>
</tr>
<tr>
<td>Cadence (Steps/M)</td>
<td>92.50</td>
<td>81.30</td>
<td>-11.20</td>
<td>-12.1%</td>
</tr>
<tr>
<td>Step Time (sec)</td>
<td>0.64</td>
<td>0.70</td>
<td>0.06</td>
<td>9.4%</td>
</tr>
<tr>
<td>Cycle Time (cm)</td>
<td>1.31</td>
<td>1.48</td>
<td>0.17</td>
<td>13.0%</td>
</tr>
<tr>
<td>Step Length (cm)</td>
<td>45.11</td>
<td>45.16</td>
<td>0.05</td>
<td>0.1%</td>
</tr>
<tr>
<td>Stride Length (cm)</td>
<td>87.37</td>
<td>85.66</td>
<td>-1.71</td>
<td>-2.0%</td>
</tr>
<tr>
<td>Base Support (cm)</td>
<td>15.03</td>
<td>13.22</td>
<td>-1.81</td>
<td>-12.0%</td>
</tr>
<tr>
<td>Single Leg (%)</td>
<td>31.70</td>
<td>30.60</td>
<td>-1.10</td>
<td>-3.5%</td>
</tr>
<tr>
<td>Double Leg (%)</td>
<td>37.10</td>
<td>40.60</td>
<td>3.50</td>
<td>9.4%</td>
</tr>
<tr>
<td>Swing Phase (%)</td>
<td>30.90</td>
<td>28.70</td>
<td>-2.20</td>
<td>-7.1%</td>
</tr>
<tr>
<td>Stance Phase (%)</td>
<td>69.10</td>
<td>71.30</td>
<td>2.20</td>
<td>3.2%</td>
</tr>
<tr>
<td>Step/Ext Ratio</td>
<td>0.48</td>
<td>0.48</td>
<td>0.00</td>
<td>0.0%</td>
</tr>
<tr>
<td>Toe In/Out (deg)</td>
<td>-3.00</td>
<td>-6.00</td>
<td>-3.00</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Table 5. Subject Three: Cane versus Walker Comparison

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Left</th>
<th></th>
<th>Right</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cane</td>
<td>Walker</td>
<td>Diff</td>
<td>%</td>
</tr>
<tr>
<td>Velocity (cm/sec)</td>
<td>61.80</td>
<td>58.00</td>
<td>-3.80</td>
<td>-6.1%</td>
</tr>
<tr>
<td>Cadence (Steps/M)</td>
<td>88.00</td>
<td>81.30</td>
<td>-6.70</td>
<td>-7.6%</td>
</tr>
<tr>
<td>Step Time (sec)</td>
<td>0.65</td>
<td>0.70</td>
<td>0.05</td>
<td>7.7%</td>
</tr>
<tr>
<td>Cycle Time (cm)</td>
<td>1.37</td>
<td>1.48</td>
<td>0.11</td>
<td>8.0%</td>
</tr>
<tr>
<td>Step Length (cm)</td>
<td>43.86</td>
<td>45.16</td>
<td>1.30</td>
<td>3.0%</td>
</tr>
<tr>
<td>Stride Length (cm)</td>
<td>84.43</td>
<td>85.66</td>
<td>1.23</td>
<td>1.5%</td>
</tr>
<tr>
<td>Base Support (cm)</td>
<td>15.71</td>
<td>13.22</td>
<td>-2.49</td>
<td>-15.8%</td>
</tr>
<tr>
<td>Single Leg (%)</td>
<td>31.70</td>
<td>30.60</td>
<td>-1.10</td>
<td>-3.5%</td>
</tr>
<tr>
<td>Double Leg (%)</td>
<td>39.70</td>
<td>40.60</td>
<td>0.90</td>
<td>2.3%</td>
</tr>
<tr>
<td>Swing Phase (%)</td>
<td>28.60</td>
<td>28.70</td>
<td>0.10</td>
<td>0.3%</td>
</tr>
<tr>
<td>Stance Phase (%)</td>
<td>71.40</td>
<td>71.30</td>
<td>-0.10</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Step/Ext Ratio</td>
<td>0.47</td>
<td>0.48</td>
<td>0.01</td>
<td>2.1%</td>
</tr>
<tr>
<td>Toe In/Out (deg)</td>
<td>-5.00</td>
<td>-6.00</td>
<td>-1.00</td>
<td>20.0%</td>
</tr>
</tbody>
</table>
CHAPTER IV
DISCUSSION

The purpose of this study was to determine if regularly ambulating with and without an ambulatory assistive device will lead to differences in the spatiotemporal and kinematic parameters of gait demonstrated by the subjects status post cerebral vascular accident. Researchers compared the gait parameters for apparent differences between no assistive devices, single-point canes, and/or front-wheeled walkers. This study encountered two major limitations. The first limitation of the study was only a limited number of participants that met criteria could be identified and recruited. This resulted in the inability of the researchers to utilize inferential statistical analysis and relate their findings to the general population secondary to an inadequate sample size. The second limitation this study encountered was the location of the output boxes on the GAITRite® walkway. Ambulatory assistive devices occasionally caught on the boxes due to the imposed narrowness. This resulted in requiring several walks to be repeated and caused subjects to become overly aware of their position and look down.

No Ambulatory Assistive Devices: Subjects versus Normal

None of the subjects in this study achieved a normal ambulatory velocity (1.3-1.6 m/s) at their comfortable pace, with Subject One, Subject Two, and Subject Three achieving 33%, 37%, and 52% of normal ambulatory velocity respectively.\textsuperscript{20} Cadence for all of the subjects followed an inverse trend with stride length increasing as cadence decreased,
with cadence being 103%, 92%, and 84% of normal, and stride length being 33%, 42%, and 62% of normal for the three subjects respectively. These results are similar to other studies that have been conducted.\textsuperscript{2,12,13}

No Ambulatory Assistive Devices versus Single-Point Cane

Both Subject Two and Subject Three had decreases in velocity (Subject Two: -5.9%; Subject Three: -7.1%) and cadence (Subject Two: -6.9%; Subject Three: -4.9%) with the use of a cane. They also displayed an increase in step time and cycle time with use of cane. Researchers observed a decrease in trunk rotation and arm swing with the use of a cane, which may be associated with the decrease in velocity.\textsuperscript{5} The decrease in Heel to heel base of support with the cane demonstrated by Subject Two (left -13.4%, right -12.8%) is consistent with previous research.\textsuperscript{34}

No Ambulatory Assistive Devices versus Front-Wheeled Walker

Velocity and cadence are decreased with the use of a walker as has been found in previous studies,\textsuperscript{4,5,33} with Subject One and Subject Three showing decreases of -9.9% and -12.8% respectively when using a front-wheeled walker. Step time (Subject One: left 17.4%, right 11.7%; Subject Three: left 9.4%, right 18.2%) and cycle time (Subject One: left 13.1%, right 14.2%; Subject Three: left 13.0%, right 13.1%) were both increased with the use of a walker. The step length of Subject One was found to increase (11.2%) on the affected side during use of a walker. The differences are most likely due to the increased base of support that allows the subjects to keep better balance and control of forward momentum, as was previously found.\textsuperscript{4,5}
Front-Wheeled Walker versus Cane

When Subject Three used a walker, his velocity (-6.1%) and cadence (-7.6%) were decreased when compared to the use of a cane. Additionally, with the use of the walker his heel-to-heel base of support decreased (left -15.8%, right -14.2%) with use of the front-wheeled walker. This is reasonable to assume because the walker itself increases overall base of support therefore the subject did not need as large of a heel-to-heel base of support. With the use of the walker, the subject had no arm swing or trunk rotation due to both hands being on the walker at all times. Subject Three was observed to have lateral shift in weight to the affected side during swing phase. See Figures 6, 7 and 8). This was demonstrated by a deviation in weight transference on the non-affected side during GAITRite® analysis. The deviation was lessened with the use of a cane compared to the walker; researchers believe this to be due to the cane forcing the subject to weight bear more equally during double limb support so he would not lose his balance. These results are similar to the limited previous research done.4, 5, 33-39

Ambulatory Assistive Devices

None of the subjects demonstrated major alterations in kinematic gait parameters between when an ambulatory assistive device was used and not used. The only consistent deviation noted was a decrease in cadence and velocity when an ambulatory assistive device was used in conjunction with an increase in step time and cycle time. However, all subjects indicated feelings of increased safety when using an ambulatory assistive device.
CHAPTER V
CONCLUSIONS

This study has examined a possible relationship between regularly ambulating with and without an ambulatory assistive device, and differences in the spatiotemporal and kinematic parameters of gait, as demonstrated by subjects status post cerebral vascular accident. All three case studies demonstrated a consistent gait pattern regardless of the use of assistive devices, with only minor differences in kinematics and spatiotemporal parameters. The small magnitude of the differences demonstrated have a strong possibility of being the result of a motor learning carryover effect, but this hypothesis will require further study. These interactions may have significant clinical applications in subjects following a neurological incident affecting gait, but require further research.

Future research should include a minimum of three areas of investigation in regards to this study. The first area of research should include the study of interactions between ambulating with and without assistive devices. “Does ambulating without an assistive device improve the utilization of the assistive device secondary to improvements in gait, balance, and posture?” The second area of research should evaluate the interaction between ambulation with a cane and a walker to identify specific interactions with alternating utilization. “Does alternating between the utilization of a cane versus a walker affect an individuals gait and balance?” The final area of research should address
differences accompanying forced increases in velocity and its affect on gait with and without the use of an assistive device. “Does ambulating at faster speeds than preferred walking speed alter gait and balance parameters with and without an assistive device?”

These three areas all possess important implications in the realm of clinical practice.

While this study lacked sufficient subjects for statistical analysis, it does indicate avenues of future research, that need to be pursued, which have been neglected up to this point. These avenues of research have a possibility of revising clinical guidelines for rehabilitation of gait on individuals following neurological incidents.

The GAITRite® system is an excellent tool for gait analysis in the clinical setting in addition to observational gait analysis. This combination allows the clinician to accurately analyze, record, and compare the objective spatiotemporal parameters of gait objectively, while being able to relate this information to the subjective data obtained from observational gait analysis. The resulting evaluation can then be used more effectively to address gait disturbances, as well as allow for the demonstration of quantifiable progress in gait training.
APPENDIX
Appendix
IRB Approval

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board
Date: 5/8/2006
Project Number: IRB-200605-385

Principal Investigator: Fulton, David; Scheibe, Emily; Zaruba, Richard; Danks, Meridee
Department: Physical Therapy
Project Title: Effects of Ambulatory Devices on Subjects Post-CVA

The above referenced project was reviewed by a designated member for the University's Institutional Review Board and the following action was taken:

☐ Project approved. Expedited Review Category No.
☐ Next scheduled review must be before: May 13, 2007
☐ Copies of the attached consent form with the IRB approval stamp dated May 20, 2006 must be used in obtaining consent for this study.

☐ Project approved. Exempt Review Category No.
☐ This approval is valid until May 20, 2006 as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.
☐ Copies of the attached consent form with the IRB approval stamp dated May 20, 2006 must be used in obtaining consent for this study.

☐ Minor modifications required. The required corrections/additions must be submitted to ROC for review and approval. This study may NOT be started until final IRB approval has been received.
(See Remarks Section for further information.)

☐ Project approval deferred. This study may not be started until final IRB approval has been received.
(See Remarks Section for further information.)

REMARKS: Any unanticipated problem or adverse occurrence in the course of the research project must be reported within 5 days to the IRB Chairperson or ROC by submitting an Unanticipated Problem/Adverse Event Form.

Any changes to the Protocol or Consent Forms must receive IRB approval prior to being implemented (except where necessary to eliminate apparent immediate hazards to the subjects or others).

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.

☐ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

Education Requirements Completed.

cc: Meridee Danks; Chair, Physical Therapy

[Signature]
Date

[(Revised 07/2004)
Appendix
IRB Project Description

IRB Form
Title of Project: Effects of Ambulatory Assistive Devices on Subjects Post-CVA

I. Project Overview

The purpose of this study is to determine alterations in gait, secondary to the transitional use of ambulatory assistive devices in subjects post CVA. The results of this study will help establish improved guidelines for the use and prescription of ambulatory assistive devices in subjects post CVA. Current literature does not fully address the use and change of gait secondary to the use of ambulatory assistive device. This study is being conducted by student researchers to fulfill the scholarly project requirement for the doctor of physical therapy degree.

II. Protocol Description

1. Subject Selection

Subjects will be recruited by word of mouth by the researchers at the UND School of Medicine and physical therapist in the surrounding community. Subjects will include healthy community members that are able to effectively and coherently communicate with student researchers. Recruitment will take place for approximately a 7 month period of time from June 1st, 2006 through December 31st, 2006. Subjects will need to be able to ambulate independently for 50 feet without use of an ambulatory assistive device and ambulate for an extended distances (at least 100’) with an ambulatory assistive device, ages 50 and older. Up to 20 subjects will be recruited; this will be an adequate amount for case studies with descriptive statistics with additional statistical testing as appropriate.

2. Description of Methodology

The subjects will be given a verbal explanation of the testing to be performed and asked if they would be interested in participating. If interested the subject will be asked to read and sign an informed consent form. A copy to the consent form will be given to the subject. The research will be performed in the UND School of Medicine. The UND School of Medicine rooms will be used when unoccupied to maintain privacy and confidentiality of the subjects. Subjects will initially be interviewed about their medical history and ambulation at home and in the community. Subjects will then be asked to walk across the GAITRite walkway, at a subjects normal walking pace in his/her everyday footwear and tested with and without their ambulatory assistive device. Subjects will start walking 6 feet before and will end 6 feet after the walkway. Two preliminary walks will be performed initially to familiarize subjects with surface. Subjects will then perform 10 trials of walking at 24 feet per trial, 5 times with and 5 times without their ambulatory assistive device. Subjects will use their own ambulatory assistive device without adjustment by the researchers. Breaks will be taken for 2-3 minutes between trials and as needed or requested by subjects. Subjects will be video taped during trials for biomechanical gait assessment by researchers visually and using the Gait Assessment Rating Score. The student researchers, under the supervision of their advisor, will be the only people to carry out the research procedures. The student researchers have been familiarized and trained in the proper use and procedures with the equipment under the direction of their advisor, a licensed physical therapist with over 20 years of experience.
Appendix
Project Description

The GAITRite system will be utilized for testing purposes in our study. The GAITRite is a 12' carpeted, low profile walkway, with 2 rows of 256 pressure-activated switches embedded. Data is collected from the GAITRite and processed on a laptop computer. Measurements include the following: cadence (step/time), walking speed, step and stride length/time.

Estimated time for the entire activity is up to 1 hour, dependent upon the amount of time required by the subject for breaks. There will be no compensation for the subjects participation. Results of the procedures will be discussed with each subject.

3. Risk Identification
There are minimal anticipated risks with the procedure, the subject is being asked to walk as they normally would in every day activity. A spotter will be present during the activities. There will be no need for the subject to be identified with the data. No link will be needed between the consent form and the data. Subjects will be identified through random numbers. The video tapes will be maintained indefinitely at the UND Physical Therapy Department for educational purposes with the subject's consent, or destroyed after three years.

4. Subject Protection
The procedure will be performed in a private room to maintain subjects confidentiality. The subject will be given verbal and demonstrative instructions prior to the procedure to minimize any risks. A spotter will be present during subjects' ambulation and breaks will be allowed as needed or requested by subjects. There will be no need for the subject to be identified. No link will be needed between the consent form and the data. Subjects will be identified through random numbers. The subjects will be provided with a copy of the consent form prior to the start of the procedure. The research data, videos tapes and consent forms will both be retained in separate locked file cabinets in the UND Physical Therapy Department for a minimum of 3 years following completion of the study. The consent forms and data will be shredded after this time. The video tapes will be maintained indefinitely at the UND Physical Therapy Department for educational purposes with the subject's consent, or destroyed after three years. Only the student researchers, the advisor, and the statistician and those people who audit IRB procedures will have access to the data.

III. Benefits of the Study

The benefits which may result from this study is the subjects will gain knowledge of their walking pattern with and without an ambulatory assistive device. The field of physical therapy and student researchers will benefit of increased knowledge of changes in the gait of subjects post CVA, with and without the use of ambulatory assistive devices.

IV. Consent Form – see attached.
Consent Form

Title of Project: Effects of Ambulatory Assistive Devices on Subjects Post-CVA

You are invited to participate in a research study being conducted by David Fulton, Emily Scheibe, and Richard Zaruba, graduate students in the Physical Therapy Department, under the supervision of their advisor, Dr. Meridee Danks of the University of North Dakota Physical Therapy Department. The purpose of this study is to identify the changes in walking of subjects post-CVA due to the regular use of assistive walking aids.

This study will help identify the changes in walking in individuals following a stroke due to the regular use of ambulatory aids. The GAITRite is a computerized walking analysis system used by researchers and clinicians to evaluate walking speed, step and stride lengths/time. The GAITRite is a 12’ carpeted, low profile walkway, with 2 rows of 256 pressure-activated switches embedded. Information from the GAITRite is collected and processed by a computer. Subjects will need to be able to walk independently for 50 feet without use of an assistive walking aid and walk for an extended distances at least 100’ with an assistive walking aid, ages 50 and older. The study consists of an interview followed by 10 trials of walking at 24 feet per trial, 5 times with and 5 times without an assistive walking aid. Trials will be video taped for biomechanical walking assessment. The expected duration for participation is one time, for up to 1 hour, dependent on the amount of break time required by subject. The results of the assessment will be mailed to each subject.

There are no foreseeable risks for the study. The subjects may benefit from learning about his/her walking pattern and physical therapy clinicians and/or researchers may benefit from results of the study. No compensation will be given for participation.

Any information from this study that can be identified with you, including video tapes, will remain confidential. Data will be identified through random numbers, no names will be used on the data. All data and consent forms will be kept in separate locked cabinets for a minimum of 3 years after the completion of this study. Only the researchers, their advisor, the statistician and those people who audit IRB procedures will have access to the data. After 3 years, the consent forms and data will be destroyed. Video tapes will be maintained indefinitely at the UND Physical Therapy Department for educational purposes with your consent or will be destroyed after 3 years.

Participation is voluntary, and your decision whether or not to participate will not change your future relations with the University of North Dakota or the Physical Therapy department. If you decide to participate, you are free to leave the study at any time without penalty.

If you have questions about the research, you may call Richard Zaruba at 791-2282 or Dr. Meridee Danks at 777-3861. If you have any other questions or concerns, please call the Research Development and Compliance office at 777-4279. You will be given a copy of this consent form for future reference.

All of my questions have been answered and I am encouraged to ask any questions that I may have concerning this study in the future.

________________________________________________________________________
Signature

________________________________________________________________________
Date
Appendix
History Form

Subject # ___________ Location: ________________ ___
Age: _______________ Male or Female

When did you have your stroke? ____________________________________

What problems have you encountered due to the stroke?
_______________________________________________________________
_______________________________________________________________
_______________________________________________________________

When, and how far, do you walk without your assistive walking aid?
_______________________________________________________________
_______________________________________________________________
_______________________________________________________________

What type of assistive walking aid do you currently use and when?
_______________________________________________________________
_______________________________________________________________
_______________________________________________________________

Have you had any other major medical conditions or surgeries?
_______________________________________________________________
_______________________________________________________________
_______________________________________________________________

Interviewer’s Initials ___________ Date ___/___/____
Appendix
Photograph/Video Release Form

DEPARTMENT OF PHYSICAL THERAPY RELEASE STATEMENT

I hereby give my permission to the Physical Therapy Department at the University of North Dakota to use my photograph (whether still, motion or television).

Name (Printed): ____________________________
Signed: ____________________________
Date: ____________________________
Address: ____________________________
City: ____________________________
State ___________ Zip Code: ____________
REFERENCES


